CRANFIELD UNIVERSITY

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Design Principles for FES Concept Development

School of Applied Sciences

MSc by Research
Academic Year: 2012 - 2013

Supervisor: Dr. Leon Williams
Second Supervisor: Dr. Heather Almond
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ABSTRACT

A variety of pathologies can cause injury to the spinal cord and hinder movement. A range of equipment is available to help spinal injury sufferers move their affected limbs. One method of rehabilitation is functional electrical stimulation (FES). FES is a technique where small electrical currents are applied to the surface of the user's legs to stimulate the muscles. Studies have demonstrated the benefits of using this method and it has also been incorporated into a number of devices.

The aim of the project was to produce a number of designs for a new device that uses FES technology. The project was completed in conjunction with an industrial partner. A review of the literature and consultation with industrial experts suggested a number of ways current devices could be improved. These included encouraging the user to lean forwards while walking and powering the device using a more ergonomic method.

A group of designers were used to produce designs that allowed the user to walk with a more natural gait and avoided cumbersome power packs. The most effective of these designs were combined to form one design that solved both problems. A 3-dimensional model of this design was simulated using computer-aided design software.

Groups of engineers, scientists and consumers were also invited to provide input on how a new device should function. Each of these groups provided a design that reflected their specific needs, depending on their experience with similar technology. Low level prototypes were produced of these designs.

A group of designers were also used to design concepts for a functional electrical stimulation device based on an introduction given by industry experts.

Each of the designs was presented to experienced professionals to obtain feedback.

A set of guidelines were also produced during the project that instructed how to create the designs.

Keywords:

Spinal Injury, Rehabilitation, Walking, Exoskeleton, Muscular Stimulation

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LIST OF ABBREVIATIONS

CAD	Computer Aided Design
EMG	Electromyogram
FES	Functional Electrical Stimulation

Design Principles for FES Concept Development

1 Background and Methodology

The aim of the project was to produce a new design for a device, which incorporated functional electrical stimulation (FES) technology, to help patients with spinal injury to walk. The device would be used primarily as a training device to help the user practice walking. FES devices apply a small electric charge to the user's body to make the muscles contract. The aim was accomplished by fulfilling a number of objectives. These objectives included:

1. Researching the causes of spinal injury and limits to mobility,
2. Scoping the current range of technology available to help spinal injury patients to walk,
3. Investigating current technology that use FES and the outcome of research that examines the technology,
4. Discovering problems associated with equipment that uses FES,
5. Investigating incorporating positive aspects of similar technology into the FES device and overcoming problems,
6. Identifying gaps in academic knowledge and opportunities for industry,
7. Creating designs that solve a number of problems caused by current technology,
8. Forming a new design that uses aspects of the designs that solves the problems of current devices,
9. Using computer aided design software to produce a good quality design of the new product,
10. Creating designs based on input from engineers, consumers and scientists,
11. Validating the designs using consultation with industry experts,
12. Producing a protocol to produce designs for FES technology.

The objectives were accomplished by utilising a number of methods. The objectives, methods used to satisfy them and the reason each method is shown in Fig. 1.

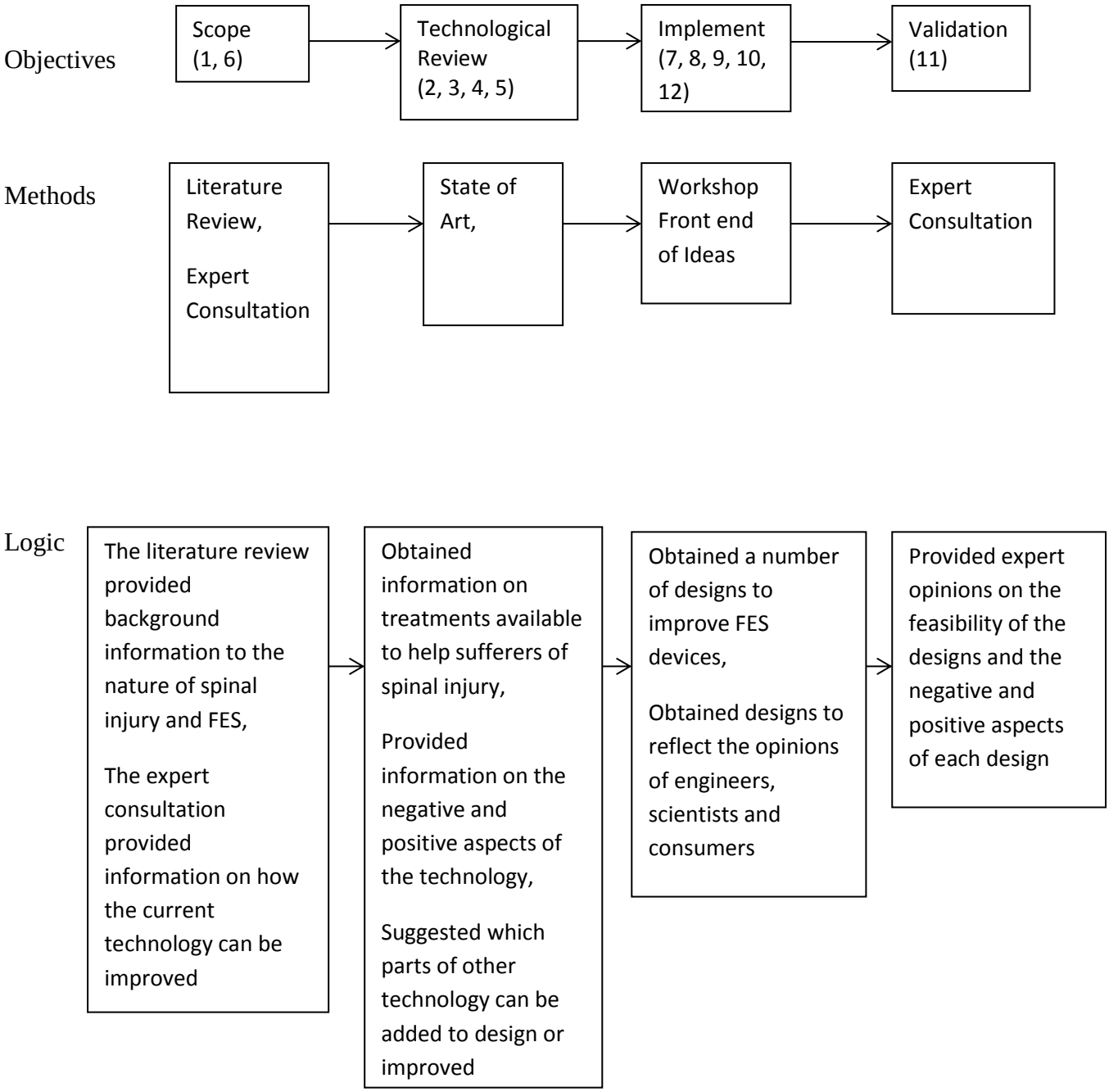


Fig. 1. A flow diagram to display the objectives of the project, how they were achieved and the logic behind the actions. The numbers inform which of the objectives were fulfilled by each action.

The project collaborated with an industrial partner to provide input and advice. The partner company provided details on the current state of the art of functional electrical stimulation towards the beginning of the project. The partner company also provided suggestions on aspects to consider during designing.

One of the considerations recommended by the industrial partner was that the device needed to encourage the user to lean forwards during walking. It was claimed that current equipment forced the user to lean backwards while walking, which could be disconcerting for the user. It was also suggested that walking while leaning forwards was more comfortable for the user and allowed them to walk with a more natural gait.

The industry partners also suggested examining how to power the device. It was claimed that other devices were powered using devices stored in large backpacks that can create problems for the user while walking. It was recommended that the device was powered using a more ergonomic method that did not provide any extra weight or hindered movement.

The literature was reviewed to obtain information about spinal injury. This provided background information about the causes of impaired movement, the effect of spinal injury on the body and methods of helping sufferers of spinal injury. Functional electrical stimulation was also researched. Information was accumulated about the mechanism of functional electrical stimulation, the effect of using functional electrical stimulation and devices which used functional electrical stimulation.

Research was also conducted into the technology available to help patients with spinal injury. The material gathered included descriptions of the devices, pictures of the device, the leading manufacturers and developers, and the positive and negative aspects of the equipment. This information helped form the designs as it displayed machines that used functional electrical stimulation and provided information about aspects of other devices that can be incorporated into the design and parts of similar equipment that needed to be improved or avoided.

The designs for the innovative device using functional electrical stimulation were created during a number of workshop sessions. The first workshop sessions used groups of product designers to produce designs to solve specific problems associated with the use of previous equipment. Other workshop activities were arranged that used design engineers, biological scientists and target users to design the most effective functional electrical stimulation devices based on their experience and expertise. The final workshop session used groups of product designers to design functional electrical stimulation equipment based on knowledge shared by the industry partners.

The work produced by the initial groups of designers was drawn onto a computer-aided design programme. The designs that seemed the most effective at solving the problems were

amalgamated into one design and a computer simulated 3-dimensional model was created. The designs produced by the groups of design engineers, biological scientists and target users were built into 3-dimensional low level prototypes.

The designs were validated during a meeting with industry experts. The industry partners examined the designs produced during the project and provided feedback on the feasibility and effectiveness of the individual designs. The experts also provided suggestions on how the project should proceed and the refinement of some of the designs.

The conclusions section of the report summarises the actions taken during the project, how the objectives were accomplished, the process that led to the production of the designs and suggest future actions that need to be taken to fully complete the project.

2 Introduction

The vertebral column (or spine) is a flexible column of bone that extends down the back of the body and is the main provider of skeletal support [1]. The spine also encloses and protects the spinal cord and attaches to the back muscles. The spinal cord is situated within the spine and forms part of the central nervous system. The spinal cord transmits impulse signals to and from the brain that dictate the movement of the body and how the body senses and reacts to stimuli. All medical terms are defined in Appendix A.

The spinal cord can become injured. If the spinal cord is sufficiently damaged, this can severely inhibit the movement and sensitivity of certain parts of the body. When the spinal cord becomes highly damaged, this can prevent the muscles in the affected body from receiving the signals from the brain and prevent the part of the body from moving.

A number of devices have been developed to enable people with different severities of spinal injury to move or train their muscles. The majority of devices can be separated into a number of different categories: wheelchairs, mobility-training devices, autonomous especial vehicles, self-ported devices and external devices [2]. A few recent devices have used a new technology known as FES to aid movement.

FES technology functions by applying electrical currents in the extracellular area to activate the nerves and contract the muscles [3]. FES can function either through surface electrodes

placed on the skin, percutaneous electrodes inserted into the muscle with a wire that cuts through the skin or through implanted stimulators and electrodes that are usually controlled through an inductive link. FES technology has been incorporated into devices to help spinal injury patients to move.

This project is being completed with the help of an industry partner. This industry partner designs equipment to help spinal injury patients to walk and is in contact with another company that is involved in creating devices that use FES. The industry partner has made a number of requests that they want to be considered into the design of the product. The industry partner wants a device that is safer and more ergonomic than other technology that uses FES.

The aim of this project is to create an innovative new design for equipment to help spinal injury sufferers to walk, using Functional Electrical Stimulation technology. The aim will be accomplished through the completion of objectives, these include:

- Decide which FES system functions the most effectively,
- Design an FES system that is safer than previous systems,
- Design an FES system that is more ergonomic than similar products,
- Form a specification for a new product,
- Develop a new product that will be marketable,
- Validate and test the new product on the target market.

2.1 Causes of Paralysis

2.1.1 Spinal Injury

There is a wide range of ways in which the spine can become damaged and limited in function. For example, it was calculated that between 15% and 40% of cases of chronic lower back pain was related to damage to some of the joints [4]. Intervertebral disc degeneration was also identified as a cause of spinal damage. Another effect of disc degeneration is a change in innervation of the intervertebral discs. Innervation is the system of nerve fibres to and from an organ. Spinal column damage can also be caused by substances attached to the spinal dura mater. The dura mater is a membrane that surrounds and protects the central nervous system and is situated close to the skull. Evidence has suggested that the connective

substance between the muscle and the dura mater can tear during injury [4]. Idiopathic scoliosis has been identified as a disease that causes damage to the spinal column. Transforaminal ligaments can form on the intervertebral foramina (opening in the vertebrate).

2.1.2 Nerve Injury and Laceration

Nerve injury can be split into three categories: neuropraxia, axonotmesis, & neurotmesis. Neuropraxia occurred when the nerve becomes damaged without affecting the connective tissue of the nerves [5]. Neuropraxia caused a loss of the ability of the nerve to conduct electrical impulses. Axonotmesis resulted in damage to the nerves without affecting the surrounding connective tissue. Neurotmesis resulted in partial or complete disruption of some of the nerves and can lead to damage to all the layers of connective tissue. Axonotmesis and neurotmesis present with a larger loss of motor and sensory functions, which can be partially or completely permanent.

2.1.3 Nerve Compressions

Nerve compression can be split into three categories. The first category refers to a nerve that was mildly compressed, but did not result in weakness of the muscle connected to the nerve. The second category refers to a nerve that experienced enough compression that the muscle weakened without dying. The third category refers to a nerve that became compressed to a degree that caused the muscle to become weakened and died, which can lead to paralysis [5].

2.1.4 Neuropathic Pain and Neural Tension Dysfunction

The peripheral nerve has the ability to tolerate motion to the limbs [5]. The loss of this ability can lead to the development of neuropathic pain and neural tension dysfunction, which can result in loss of limb function. These effects are caused by alterations of the neurophysiology of the body.

2.1.5 Cerebral Palsy

Cerebral palsy was a group of permanent disorders that affects the development of posture and movement, which cause activity limitation and are attributed to damage experienced by the developing brain [6]. The primary symptom of cerebral palsy is limitations to movement, but other symptoms can also occur, such as epilepsy, other problems with the muscles and disturbances to sensation, perception, thinking, communication and behaviour. Cerebral palsy can be described as spastic (hemiplegia, diplegia or quadriplegia), dyskinetic (choreoathetoid or dystonia), hypotonic or mixed (Table 1).

Table 1, a table to display the symptoms experienced by an infant suffering from cerebral palsy.

Age of Infant	Symptoms of Cerebral Palsy
Less than 2 months	Delayed motor milestones, toe walking, persistent fisting, increased rate of growth of head circumference, seizures, irritability, poor suck, early development of handedness and scissoring
Over 2 months	Poor head control, stiff legs and scissoring
Over 6 months	Poor head control, unable to sit unsupported and prefer to use only one extremity
Over 10 months	Crawl using one hand and foot while dragging the other hand and foot and unable to stand without support
Over 12 months	Unable to crawl or stand without support
Over 24 months	Unable to walk

2.1.6 Myelomeningocele

Myelomeningocele is a disease that leads to loss of muscle ability [6]. Myelomeningocele was caused by defects in the nervous system. Myelomeningocele refers to the development of defects which cause the protrusion of parts of the nervous system.

The effects of the causes of paralysis on the body were listed in table 2. This information was useful as it described the problems experienced by people who may use the FES device and how the device could be designed to alleviate these symptoms. More detailed information about each of the causes of spinal injury is contained in Appendix C.

Table 2, a table to summarise the effects of neurological diseases on the body

Causes of Paralysis	Severe Effects
Spinal Injury	Back pain, chronic neck pain, disturbed balance, nerve root entrapment [4], headaches [4,7], periodic low back pain [8] and inability to reposition lumbar spine [9]
Nerve Injury and Laceration	Loss of motor and sensory functions [5], loss of control of organs [10]
Nerve Compressions	Weakened muscles and paralysis [5]
Neuropathic Pain and Neural Tension Dysfunction	Loss of limb function, pain running from a focal point "along a track", clusters of pain [5], spontaneous pain [11], deep pain, superficial pain, paroxysmal pain, delayed pain and nerve damage [12]
Cerebral Palsy	Motor dysfunction, epilepsy, cognitive difficulties, metabolic disturbances, communication difficulties, impairment to sensory system and behavioural difficulties [6,13]
Myelomeningocele	Loss of motor function, loss of sensory function, hydrocephalus development, damage to voice function and breathing difficulties [6]

2.2 Methods of Managing Spinal Injury

2.2.1 Wheelchairs

Wheelchairs have been identified as the optimal solution to a lack of mobility. Wheelchairs can be separated into two categories, manual and automotive. Manual wheelchairs refer to wheelchairs that the user has to move using their own strength. Automotive wheelchairs are wheelchairs that use robotic systems that move the wheelchair [2].

2.2.2 Parapodium

A parapodium is an orthosis that allows the patient to stand by supporting the chest, buttocks, anterior knee and heel [14] (Fig. 2). The device allows either a swivel or swing-to gait, which determines if the user can use their arms while using the device. The parapodium also allows

the patient to sit while the device is in use, which makes it suitable for children to use in a school setting.

Fig. 2 An example of a parapodium device [15]

The parapodium is usually recommended for very young children and they can learn to use it with a walker as they grow older [14]. The parapodium can be replaced by other orthoses as the patient grows older and achieve a better sense of balance, also, the parapodium can be difficult to remove independently. A number of benefits of standing have been identified, as well as reasons for the patient to avoid standing (Table 3).

Table 3, a table to display the positive effects of standing and associated diseases that can worsen with standing

Positive Effects of Spinal Injury Patients Standing	Diseases Associated with Spinal Injury that can Worsen with Standing
• Positive psychological effect of user being at eye-level to other people, • Stretches the muscles of the lower leg, • Provides pulmonary hygiene, • Promotes the positive effects of weight-bearing, • Enables exercise and strengthening, • Widens the range of movements and balance for the user, • Encourages the patient to achieve ambulation	• Severe osteoporosis, • Heterotrophic ossification which prevents movement of the lower extremity, • Poor joint integrity, • Significant pain, • Impaired hip or knee flexion contractures, • Cardiopulmonary compromise, • Significant scoliosis or kyphosis, • Significant windswept deformity, • Uncontrolled hypotension, • Skin breakdown

An alternative to the parapodium would be to move the user's body using mechanical forces, rather than the user's own muscle power.

2.2.3 Exoskeleton

An exoskeleton is a device that actively helps the user to move (Fig. 3). The exoskeleton is designed to fit around either the user's entire body or part of it. The exoskeleton also uses mechanical systems to move the body. An exoskeleton is different to a parapodium because it uses a mechanical system to move, the legs can move independently of the arms and it allows a more natural mode of walking. Exoskeletons also function using a number of processes, sensing how the user initiates movement, actuation (moving the device), and source of power [2].

Fig 3. An example of an exoskeleton [16]

Exoskeletons were very complex and expensive systems. An alternative would be to use a simple device that encourages the user to walk using the user's own movements.

2.2.4 Parallel Bars

Parallel bars are the most basic form of mobility training. The device helps people regain balance, strength, range of motion, independence and recover from injury [2]. The device consists of two bars, parallel to each other, raised to waist level, which the user can hold while performing movements that use more than one joint and muscle. This technology has been proven to be a useful method of rehabilitation. The device requires the involvement of two therapists to move the user's legs; therefore, it cannot be used by the patient independently and also requires commitment and substantial effort on behalf of both the user and therapists.

Other technology was available that provided support needed to practice walking, but performed a more active role in determining the precise movements of the user during walking.

2.2.5 Treadmill-training Devices

Treadmill-training devices use a treadmill during mobility training. These devices function by the patient re-learning walking movements through repetition and task-orientated training [2]. This technology allows the patient to concentrate on the lower limb movement, rather than balance, during walking (Fig. 4). Some devices also utilise a partial body-weight support to support the user's body weight and lighten their load during walking.

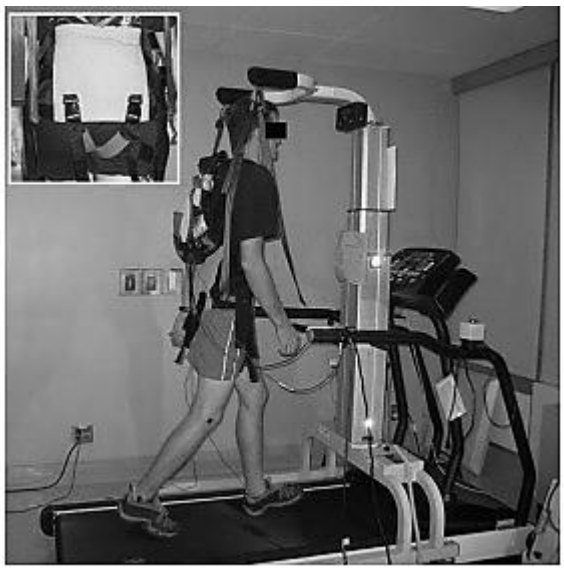


Fig. 4, an example of a treadmill-training device [17].

The main function of treadmill-training devices was to encourage users to re-learn to walk [17]. Teaching the user to walk can be accomplished using a number of gait training activities (Table 4).

Table 4, a table to display the methods of gait training and how previous devices have performed the activity

Gait Training Activity	Description	Methods of Incorporating Activity into Device
Trajectory tracking	Proportional feedback position controllers and joint angle gait trajectories are used to guide the user's limbs on a fixed trajectories	Teach and replay (trajectory is recorded during manual assistance and repeated during robotic assistance) and adaptive robot (device only provides force if needed)
Impedance control	Position of the device and inner force are used to control force exerted by actuators to move the machine	Triggered assistance (device activates if user is unable to complete movement) and force field control (keeps movement along a virtual path)
Adaptive control	Motion of the device initiated by physical interaction between user and device, allowing the user to control the motion of the machine	Teach and replay (data from manual exercises between user and therapist are used to programme the device) and algorithms

An alternative to the user walking on a treadmill would be to allow the user to walk over ground.

2.2.6 Ambulatory-training Devices

Ambulatory-training devices are similar to treadmill-training devices. Ambulatory-training devices, unlike treadmill-training devices, do not require the use of a treadmill, instead it uses over ground training (Fig. 5). These devices use less equipment than treadmill-training devices [2]. This technology provides dynamic assistance to help the movements of the user and allows the user to walk with the proper upright posture.

Fig. 5, an example of an ambulatory-training device [2].

Other devices did not rely on the user moving over a surface. Instead, a number of devices function by directly moving the feet of the user.

2.2.7 Feet-Manipulator Training Devices

Feet-manipulator training devices help train the user's mobility by focussing on the feet. The user's feet are attached to robotic manipulators that support and gently simulate walking [2]. The user wears a harness attached to a steel frame and rests their feet on plates. The plates can be programmed to imitate walking situations, such as walking on level ground, tripping, slipping or using stairs (Fig. 6). Practice of walking movements exercises the slack muscles between the hips and toes.

Fig. 6, An example of a feet-manipulator training device [2]

Not all devices were complex machines which encased the user. Some devices were much smaller and only affected the part of the body unable to move properly.

2.2.8 Orthoses

Orthoses are devices carried by the user to improve the function of movable body parts. Orthoses are designed to offset hindrance to mobility and help the movements of the user [2]. The devices improve the functionality of the affected limbs and allow the user to perform a wide variety of movements (Fig. 7). These devices can either be active (the equipment provides the energy needed to perform movements) or passive (the user moves the limb along with the orthosis).

Fig. 7, An example of an orthosis [2]

Simpler devices were available that used less mechanical components and provided support, instead of movement.

2.2.9 Canes

Canes are external devices used to help the user's balance. The canes provide an increase in gait stability and have been shown to prevent falls [2].

Similar devices were available that provided more support.

2.2.10 Crutches

Crutches are external devices that directly support the body. The crutches provide greater stability and balance during walking. The crutches also provide greater weight support than canes. A number of problems have been identified with using crutches. These problems include the crutches being cumbersome and providing an unnatural gait [2].

Other devices were developed that provided support. These devices were more complex and more mechanical, but required less effort by the user and were smoother.

2.2.11 Walkers

Walkers are external devices that support the user during walking and move using the user's locomotion. The use of the walker increases the user's base of support, which allows the user to maintain a higher level of balance and can change their position more freely [2]. The walkers can also incorporate stabilising reaction forces to improve the stability of the user. Walkers are classified as either conventional (are simply pushed along the ground) or smart (include robotic and electronic components that improve navigation, gait monitoring and weight support).

Devices were also developed that dictated how the user stood, instead of providing support during walking.

2.2.12 Standing Frames

Standing frames are external devices that allow the user to stand. The standing frame provided external support and secured the knees and hips to allow the user to remain in a passive standing position [18]. Standing frames can be stationary or wheeled. Wheeled standing frames have been shown to improve independent mobility and strengthening by allowing the user to propel themselves along level surfaces [14].

2.2.13 Functional Electrical Stimulation Devices

FES technology functions by applying electrical currents in the extracellular area to activate the intact lower motor neurone and contract the muscles [19]. The stimulation is conducted in a coordinated way to achieve functional movements. A variety of methods (such as joysticks and switches) can be used to allow the user to control movement and enable the user to regain control over their paralysed muscles.

FES can function either through surface electrodes placed on the skin, percutaneous electrodes inserted into the muscle with a wire that cuts through the skin or through implanted stimulators and electrodes that are usually controlled through an inductive link. Functional electrical stimulation technology has been incorporated into devices to help spinal injury patients to move.

FES devices consist of three components: a controller, a stimulator, and an electrode [20]. The controller uses either a microprocessor or microcontroller to control the flow of power and generate regular electrical impulses. The function of the controller can either be open-loop or closed-loop, depending on whether the signals produced by the device will be monitored. The stimulator produces the pattern of electrical current pulses used to stimulate the muscle. The pattern of current depends on the pulse amplitude, pulse width, pulse shape and pulse frequency. Figure 8 displays the components of a functional electrical stimulation device.

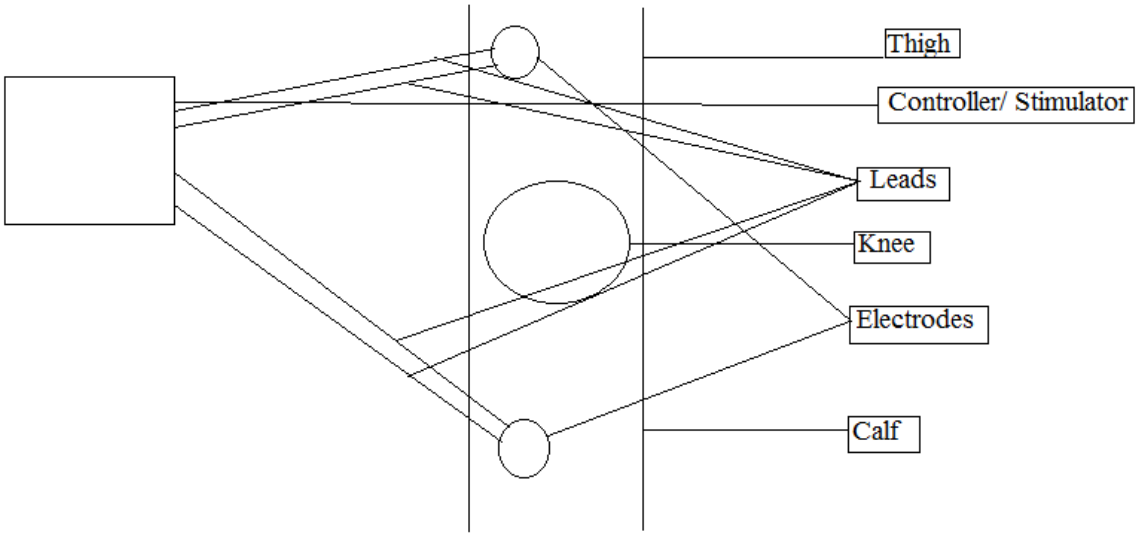


Figure 8, a diagram to display the main components of a simple functional electrical stimulation device.

The system of functional electrical stimulation must also function with the limitations and characteristics of the tissue it was stimulating. Improper stimulation of the tissue can cause a number of problems, including pain, tissue damage, fatigue, corrosion of the electrode or interface and poor selectivity [21].

One implanted FES device is the eight-channel implantable receiver-stimulator (IRS-8). The IRS-8 is implanted into the body of the user and is controlled using radiofrequency signals from an external source [19]. Another device is the implantable stimulator-telemeter (IST). This device uses signals from physical sensors, telemeters the data for processing externally and then receives control and power information to stimulate the neural tissue. The IRS-8 device is primarily used to help the hands grasp and release, but has been shown to aid standing-transfer and walking for spinal injury patients. IST devices can stimulate grasp and release in users hands, but can also help forearm pronation and elbow extension.

Another implanted FES device is the radiofrequency-powered and EMG-controlled implant. The device controlled using the EMG from the diaphragm and emits long, ramp-shaped impulses [22]. The impulses activate denervated muscles, using the structure of the neurons, without activating adjacent neural structures. These implants are specifically designed to function on denervated muscles.

An FES device was developed that used a new method of stimulating the muscles. The device was designed to be portable and flexible. The machine also used a multichannel system and flexible waveform generators to improve muscle selectivity and decrease the amount of current used, which reduced the pain and fatigue experienced by the user [21]. The device was powered using four AA batteries and was controlled using a USB communication interface. The two main components of the new technology were an electrostimulator and switching circuits. The source of the current in the electrotransmitter was a closed loop circuit, with a high voltage operational amplifier and a microcontroller. The switching circuits consisted of a field of microelectronic arrays to apply unique excitation signal sources to multiple electrodes.

Devices were developed that used FES to help the user achieve an appropriate standing posture. The main aspect to helping the user to obtain a good posture, without needing to use their arms to stabilise themselves, was to ensure that the ankle and hip joints were stiff and the knees and hips were in the correct position [23]. The two devices that were created used either a single-link or two-link closed-loop FES posture control. The single-link closed-loop FES posture control uses a frame, to limit the user's movement, and an apparatus to ensure that the user is only able to move the ankle joint. The two-link closed-loop FES posture uses the same frame and a closed-loop system of functional electrical stimulation to control the ankle joint, while the upper body remained under voluntary control.

These devices did allow the user to stand for short periods of time; however, other weaknesses were identified. Neither device was able to function if the user experienced major perturbations. The devices were also impaired if the user has secondary medical problems (such as muscle weakness and fatigue). The adaptive control function of the devices needed to be used with caution, as it was limited when the user used the device for quiet standing [23].

An implanted electrical stimulation device was used to restore injury after spinal injury. A middle-aged man with cervical spinal cord injury had multichannel pulse generator and

intramuscular stimulating electrodes implanted to activate the muscles in the lower back region. This intervention was proved to improve a number of physiological functions, such as spinal alignment, seated posture, pulmonary function, trunk stability and reach. The stimulation of the hip and trunk muscles was also shown to improve the user's ability to perform everyday tasks and enable independent wheelchair use and bed mobility [24].

The use of FES has also been shown to provide more specific benefits to the user. FES has been shown to help rebuild damaged bones. An eight-channel-stimulator was used to condition the muscles before the subjects used an FES-tricycle. The device used the same eight-channel-stimulator and electrodes were applied to the gluteal, quadriceps and hamstring muscles to stimulate these muscles to produce a cycling motion. The system was shown to encourage the formation of bone in the distal femur, with a small effect in the femur and no change in the tibia. The muscles also showed some slight improvement [25].

It has also been demonstrated that the specific speed of cycling affected muscle growth. The subjects used an isokinetic FES cycle ergometer, with one leg set to cycle at 10 revolutions per minute and the other leg programmed to cycle at 50 revolutions per minute. Both speeds caused an increase in circumference at the distal and middle regions of the thigh, but the lower speed caused a greater increase in circumference. The lower speed also caused a greater gain in electrically evoked isometric torque in the quadriceps. This suggests that using the cycle at lower speeds lead to a greater muscle hypertrophy and electrically stimulated muscle strength than higher speeds [26].

FES cycling has been further proven to help ankle function and leg conditioning. The subjects used an isokinetic FES cycle ergometer with a pedal boot that allowed the ankle to flex during cycling. The optimal stimulation timings to induce flexing were observed by altering the stimulation angles of the shank muscles, before applying the stimulation to standard functional electrical stimulation cycling. It was discovered that freeing the ankle joint to rotate during cycling was safe. It was also found that shank muscle stimulation and repetitive ankle joint movement can improve ankle flexibility and leg conditioning, however, more research was needed to decide what design of ankle support could provide the maximum benefit of shank muscle activation [27].

FES cycling has also been proven to help patients suffering from neuromuscular impairments. The specific equipment used an eight-channel surface device to deliver electrical stimulation to the user's muscles and cause them to contract in sequence. A newly

designed seat, consisting of a larger seat with a head rest, mesh backing, foam padding and a seat belt, was found to produce trunk and pelvic support and achieve a smooth pedalling motion. The pedals were also replaced with orthoses that allowed the calf to pivot, which were demonstrated to allow for greater ankle flexibility than other orthoses [28].

It has been shown that FES can improve aerobic capacity. A rowing device that features FES technology was used as it was a large muscle exercise and it involved both the innervated upper body and electrically stimulated lower body. The equipment used a seating system that provided trunk stability, while keeping the legs moving in the correct motion and preventing hyperextension and hyperflexion of the knee joints. A voluntary thumb press was used to allow the user to activate a four-channel electrical stimulator (which stimulated the quadriceps and hamstrings) to ensure that the stimulation functioned at the correct time [29].

The subjects using the FES rowing machine underwent a period of preliminary FES training. This ensured that the users had the needed amount of leg muscle strength and endurance to perform the rowing action. The subjects were then able to use the rowing machine. It was shown that using this type of exercise can increase the user's maximal aerobic capacity, power output and active muscle mass. It was also demonstrated that the subjects developed an almost 30% increase in aerobic capacity and a greater consumption in oxygen than people undergoing lengthy training periods [29].

Neuromuscular electrical stimulation was also found to have an effect on aerobic fitness in spinal cord injury patients. Four electrodes were placed on the quadriceps and hamstrings and a neuromuscular electrical stimulation device was used to stimulate the muscles. The training was found to increase peak oxygen consumption and peak heart rate in the subjects. It was concluded that the device was an effective method of improving aerobic fitness in spinal cord injury patients [30].

FES-assisted training can also limit damage to bones. Many spinal cord patients experience osteopenia, where the muscles atrophy (or die) and the bones progressively weaken. The subject's quadriceps was stimulated to contract against an isokinetic load. After the training, the distal femur and proximal tibia had recovered 30% of the bone lost through osteopenia and a lot of the strength was regained, however, the mid-tibia region and the sides were not affected. The device was considered to be able to partially reverse the effects of osteopenia, but was unable to prevent the bone loss completely [31].

A number of advantages and disadvantages associated with each device used to manage spinal injury were listed in table 5. This information was useful as it suggested aspects of each device to incorporate into the design. It also clarified parts of each device that should be improved or avoided when designing the new device. More detailed information about each of the methods of managing spinal injury is contained in Appendix C.

Table 5, a table to list the advantages and disadvantages of a range of equipment used to manage spinal injury

Equipment	Advantages	Disadvantages
Wheelchair	Optimal solution for people suffering from lack of mobility [2]	User constantly sitting down can cause health problems [2,32,33], user can be affected by vibrations [34] and the user may not learn to use it properly [35]
Parapodium	Relieves the pressure of the load on the body, prevents friction between foot and floor, allows user to feel safe and secure, provides health benefits of standing and is suitable for young children [14]	The user cannot use their hands while walking, it requires lessons to use properly, it forces the user's legs to swing with each movement, standing still can cause health problems and it cannot be removed independently [14]
Exoskeleton	Does not require training, requires little energy to use, can have additional functions added to it, can improve the improve the power of damaged parts of the user's body [16,36] and it can mimic the movements of the user [37]	Cannot perform complex movements, performance can be affected by a wide range of variations and it uses unsuitable power sources [37]
Parallel Bars	Helps user regain balance, strength, range of motion, independence and recover from injury [2]	Does not provide realistic walking conditions, user can become over reliant, it cannot be used independently and requires

		substantial effort by user and therapist [2]
Treadmill-training Devices	Allows user to concentrate on movement and not balance, can support the user's body weight [2], a number of gait training activities can be performed [17], can be adjusted for different users [38], required little time for user to learn [39], safe [40], improves gait [41] and can be used with a wide range of users [42, 43, 44, 45, 46]	User has to be actively engaged in procedure, method to support body weight can uncomfortable, requires a lot of effort on behalf of therapists and devices would also need to use either cables and rigid linkages or heavy machinery to function correctly [47]
Ambulatory-training Devices	Uses less equipment than similar devices, user learns to walk with proper posture [2], supports body weight, can be adjusted for different users, improves gait and heart rate, can be used with other technology [48], safe [48, 49, 50], allowed user to perform challenging movements [49] and functioned with a range of users [51, 52]	User has to be actively engaged in procedure, method to support body weight can be uncomfortable [53]
Feet-manipulator Training Devices	Can be used with a wheelchair, forces muscles to follow, correct movements [2], simulates different situations [2, 54, 55], allows therapist to control the user's movements [56], safe [57, 58, 54] and can	User has to be actively engaged in procedure, method to support body weight can be uncomfortable, can affect the user's normal sense of balance and the user's walking momentum can be hindered [54]

	be adjusted for different users [56, 57]	
Orthoses	Allows the user to use affected limb, can perform a range of functions, improves the health and self-esteem of user [2], safe, flexible, adjustable for different users and can be attached to an backpack [39]	Can be uncomfortable, difficult to use, affect the aesthetics of the user [2]
Canes	Can sense the desired pace and direction of user's walk, can detect obstacles [59, 60] and provides stability [2]	Provides little support and the user can easily fall backwards [18]
Crutches	Provides stability and balance, supports user's weight [2]	Are cumbersome and encourages and unnatural gait [2]
Walkers	Easy to use, can perform multiple functions, gait and walking speed can improve, can help user move upstairs, provides stability, adjustable for different users [2], avoids obstacles and provides navigation tools [59, 61, 62, 63, 64]	Some devices require a high upper body strength and cognitive ability to use, can produce an unnatural and slow gait, unable to detect stairs, a large portion of user's abandon the device, need more space to use and require more energy [2] and can cause falls [18]
Standing Frames	Positive health effects of standing, does not require modifications to home or work, improves social interactions and allows independent mobility [2]	Some devices need a carer to help user into the device [2] and negative health effects of standing [14]
Functional Electrical Stimulation Devices	Improvements in gait and walking speed [23, 24, 27], helps rebuild bones [25, 31],	Some devices need to be implanted [19], can cause harm if used incorrectly [21] and does

	strengthens muscles [26], improves fitness [29, 30] and functions on a range of users [24, 28]	not function correctly with some users [23]

3 Methods

The project was to design an innovative FES device to help spinal injury patients to walk. An industry partner involved with the project had identified a number of problems associated with similar devices. These problems were the devices were not safe and were not ergonomic.

The industry partners claimed that current FES devices were not safe. It was suggested that the technology did not provide sufficient stability and there was a high risk of the user falling while using the equipment. It was also noticed that the devices were not used unless medical personnel were present (for example, to ensure that they are able to catch the individual should they fall). This suggests that the technology is not suitable for use outside the medical or laboratory environments.

The industry partners claimed that current functional electrical stimulation devices were not ergonomic. It was claimed that the devices were powered using large backpacks, which were also very heavy and could cause problems when the device is in use. It was also suggested these devices were unable to turn corners, which only permitted the user to walk up and down straight corridors. It was concluded that the current functional electrical stimulation devices were unsuitable for daily use.

The industry partners found that FES devices should allow the user to walk with a normal gait. It was noticed that many devices allow the user to lean backwards while walking; however, it was more correct for the user to lean forwards while walking to imitate normal walking. The industry partners requested that the current device should encourage the user to lean forwards.

The specification from the industry partner was to design a new FES device that was safer and more ergonomic than the previous technology. The industry partners provided a design of a device that was intended to allow spinal injury patients to walk, but did not use functional electrical stimulation technology.

A number of methods of developing designs were suggested (Table 6).

Table 6, a table to display the different methods of producing designs and the strengths and weaknesses of using the different approaches.

Method of Developing Designs	Benefits	Limitations
Workshop	- Able to produce a large number of designs quickly, - Able to produce responses from a wide range of contributors	- Designs may not be feasible, - Difficult to arrange the workshop with an appropriate number of contributors
Expert Input	- Designs will be of good quality, - Will be able to use experience and knowledge to inform designs	- Experts may be unavailable or unwilling to join workshop, - Expert will only be able to provide opinions on individual experience
Ideas from Literature	- Designs would reflect tested ideas about build, - Information would be impartial and consider a range of aspects of the design	- Difficult to obtain feedback on the designs, - Need to distinguish between reliable and unreliable studies

A group of three product designers were selected for a workshop. These designers were contacted by e-mail to arrange a suitable time for the workshop to take place. A date and time was agreed and a room was booked for the meeting.

The aim of the workshop was to design modifications to the original device so that either the device would encourage the user to lean forwards or would be powered by a more ergonomic power source. Three designers were selected for the workshop because the workshop was intended to solve a specific problem and a small number of contributors were required to produce solutions. The designers each produced a design that would encourage the user to lean forwards. The designers also produced a design that would power the device. A total of six designs were produced during the workshop activity.

The six designs were then drawn using computer-aided design software. The designs were shared with the industry partners and they approved of them. The design that represented the most effective method of powering the device and the design that showed the most efficient method of encouraging the user to lean forwards were amalgamated into one design. A 3-dimensional model of this design was created using computer-aided design software.

The computer-aided design software used during the project was called Rhinoceros 5 Evaluation. Lines could be drawn across a grid to produce 2-dimensional designs using this

software. Closed shapes can be formed by joining a number of lines together. The closed shapes can be transformed into surfaces using a special feature, which can then be raised or lowered to form 3-dimensional shapes. A number of 3-dimensional shapes can be produced and positioned to produce a 3-dimensional representation of the design. A special feature can be used to transform the design from a collection of smaller shapes into one larger shape.

The 3-dimensional design was designated as reflecting the voice of the design engineer (because it represented a design that was functional). A 3-dimensional model was built based on the design. A 3-dimensional model was built to reflect the voice of the target user, because it was comfortable and smaller. A 3-dimensional model was also built to reflect the voice of the biological scientist, because it resembled the bare essentials needed for an FES device to function.

A second workshop was arranged that consisted of eight product designers (Fig. 9). The industry partners were invited to attend and a date was arranged that was convenient. An invitation letter was written and e-mailed to the administrators of the Engineering, Health and Design Departments of the University. A room was booked for the workshop. The industry partners were available to provide a critique of the designs and described the background to functional electrical stimulation. Eight designers were required for the workshop because the aim was more general and it was considered that the designers would produce more effective designs if they discussed the problem in small groups.

The workshop began with the industry partners providing a background to functional electrical stimulation. The progress of the project was presented to the workshop and the group was requested to produce designs for an FES device based on the knowledge provided. A number of designs were produced during the workshop session.

The designs were presented to the other members of the group. The industry partners provided feedback on the positive and negative aspects of each of the designs. The designs were gathered after the workshop session.

Fig. 9. A photograph of a workshop to produce designs for an innovative new device that uses functional electrical stimulation.

A final design could be produced by combining the different designs produced during the project into a hybrid design. The designs to reflect the voice of the engineer, the voice of the scientist and the voice of the consumer all considered different perspectives and what aspects should be added to the device to improve the design. Producing a hybrid design to incorporate these different viewpoints into the device would allow the design to fulfil the criteria set by the users and experts and optimise the efficiency of the device. Figure 10 displays how a hybrid design could be produced.

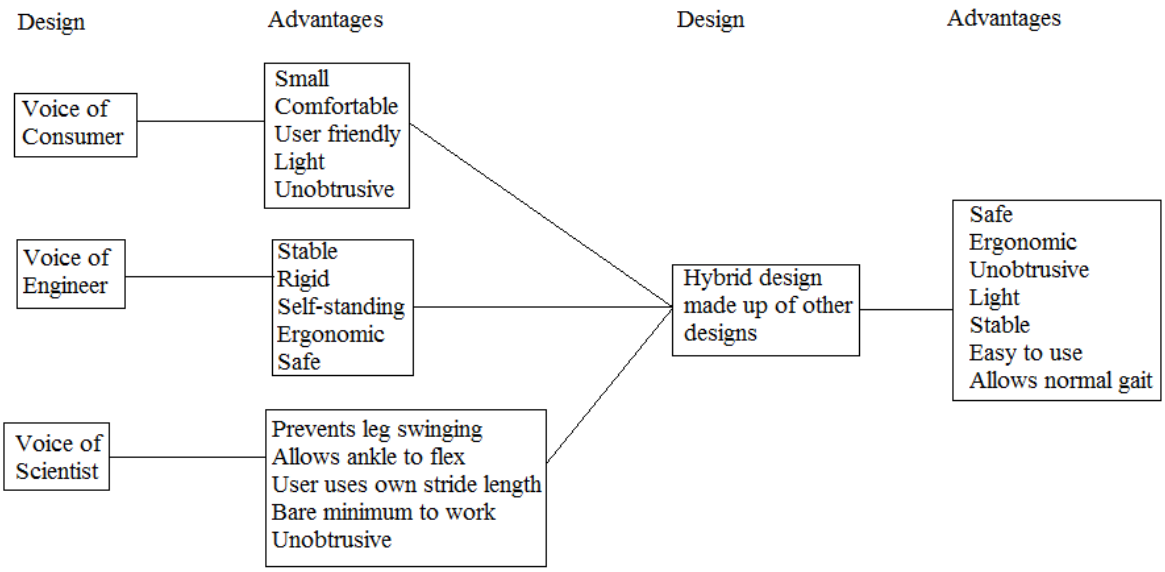


Figure 10, a flow diagram to demonstrate the production of a hybrid design and the advantages of the new design

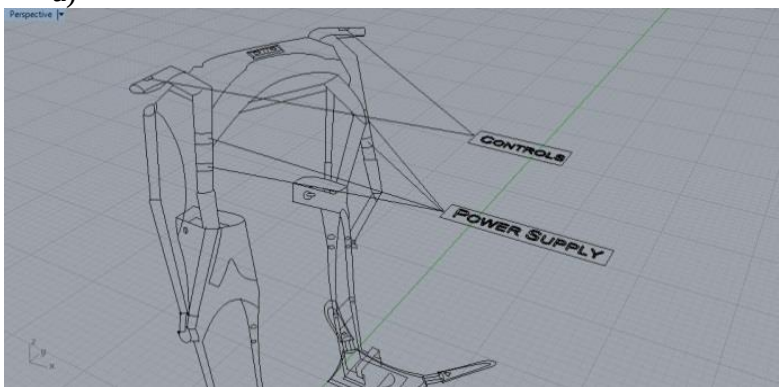
The hybrid design could be created during a workshop session. Invitation letters would be sent to invite biological scientists, design engineers and potential users to attend the workshop. This workshop would be used to produce a final design that reflects the priorities of the user, scientist and engineer.

4 Results and Discussion

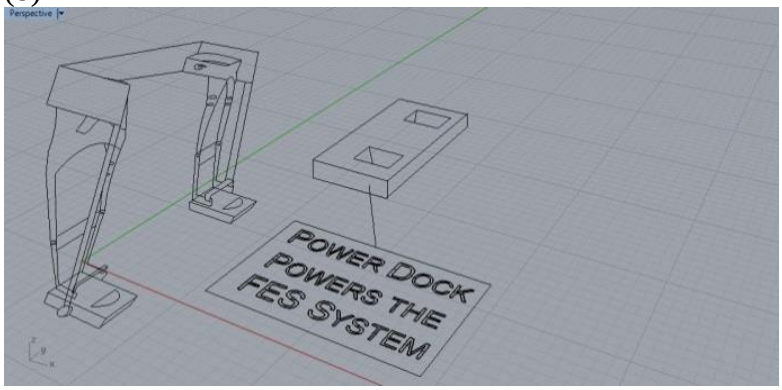
The industry partners examined the designs for an innovative FES device and provided feedback. The designs reflecting the voice of the engineer were considered to resemble a medium-sized exoskeleton. One of the problems associated with constructing an exoskeleton would be that it would need to be custom-made to fit the users; therefore, it would be unsuitable for mass marketing. Another problem was that exoskeleton's are very expensive to build.

The six designs were drawn using computer-aided design software. These designs were intended to either demonstrate a more ergonomic method to power the FES device or display a method of encouraging the user to lean forwards while using the device. Figure 11 displays these designs.

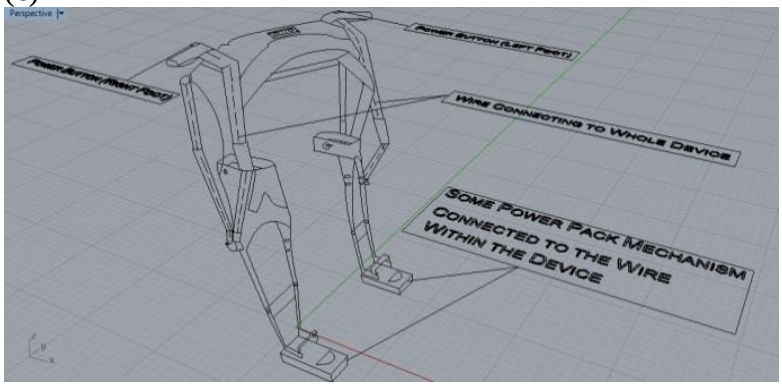
a)


CONTROLS
POWER SUPPLY

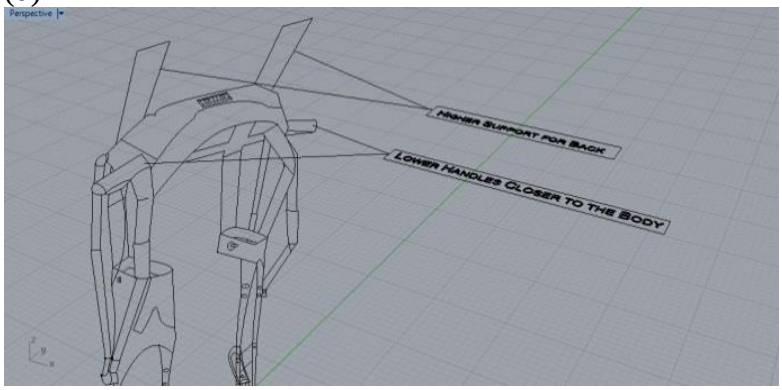
(b)


POWER DOCK
POWERS THE
FES SYSTEM

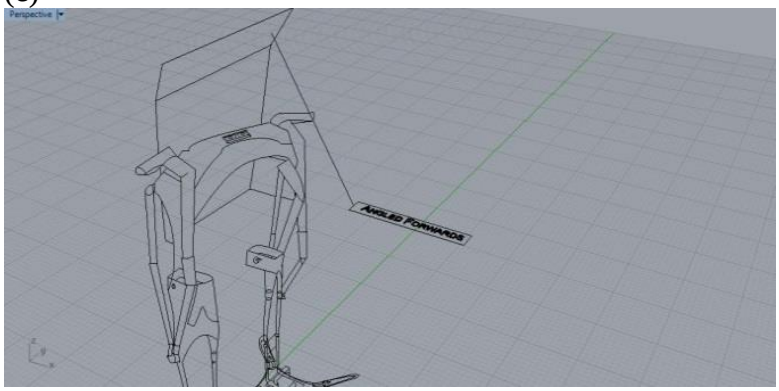
(c)


WIRE CONNECTING TO WHOLE DEVICE
SOME POWER PACK MECHANISM
CONNECTED TO THE WIRE
WITHIN THE DEVICE

(d)


HIGHER SUPPORT FOR BACK
LOWER HANDLES CLOSER TO THE BODY

(e)



(f)

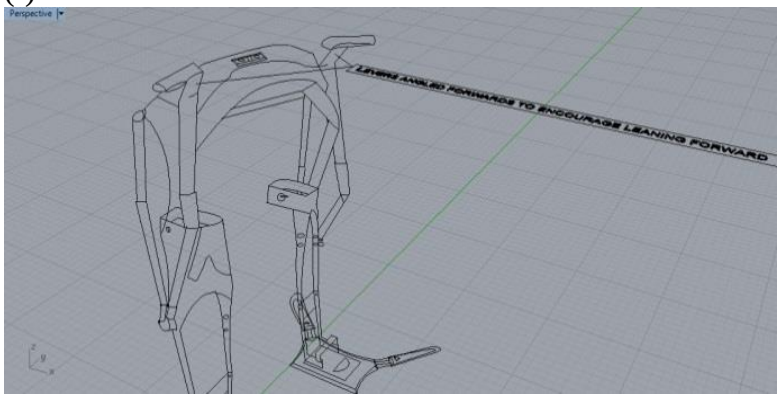


Fig. 11, 2-dimensional designs for new FES devices. (a), (b), (c) Designs that modify the way the device is powered. (b), (e), (f) Designs that encourage the user to lean forwards.

The design showing the most ergonomic way of powering the device was combined with the design displaying the most effective method of encouraging the user to lean forwards to create a new design. A 3-dimensional model was developed using computer-aided design software. This design was considered to reflect the perspective of a design engineer and was stable, functional and self-standing. Figure 12 displays this 3-dimensional design.

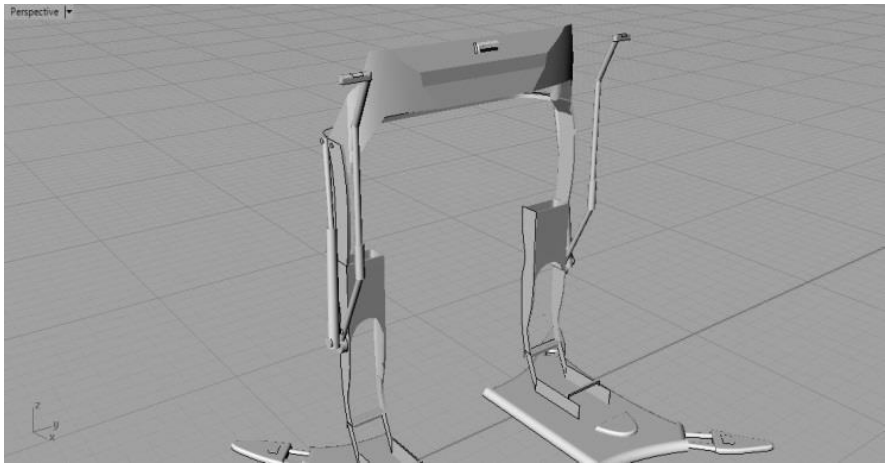


Fig. 12. A 3-dimensional design that reflects the voice of the engineer.

One of the suggestions to provide a less cumbersome method of powering the device was to attach a power supply to the bars of the device (Fig. 11 (a)). This design was considered feasible as the FES system could be powered using medium-sized rechargeable batteries.

The other designs used a power supply located within the feet of the device, which would be charged using specially designed equipment that the feet could fit into (Fig. 11 (b)). It was considered realistic for the power supply to recharged using the charging technology. It was recommended to avoid placing the power supply within the feet as this could make them heavier and affect the balance of the user.

The designs also made the feet of the device smaller to improve the user's ability to walk along narrow surfaces. This was considered to decrease the stability of the device and prevent it from remaining upright. It was suggested to use bigger feet and obtrusions to improve the ability of the device to grip the ground.

It was considered beneficial to design methods of encouraging the user to lean forwards while using the device to replicate a natural gait. It was suggested that wheelchair users were accustomed to leaning backwards whilst using a wheelchair as this provided a centre of gravity. When wheelchair users used a device that required them to stand upright, it was found to be disconcerting to suddenly being required to lean forwards and this may provide a frightening and uncomfortable experience for the user. Leaning forwards was also more recommended for a walking activity and not while the user was standing still.

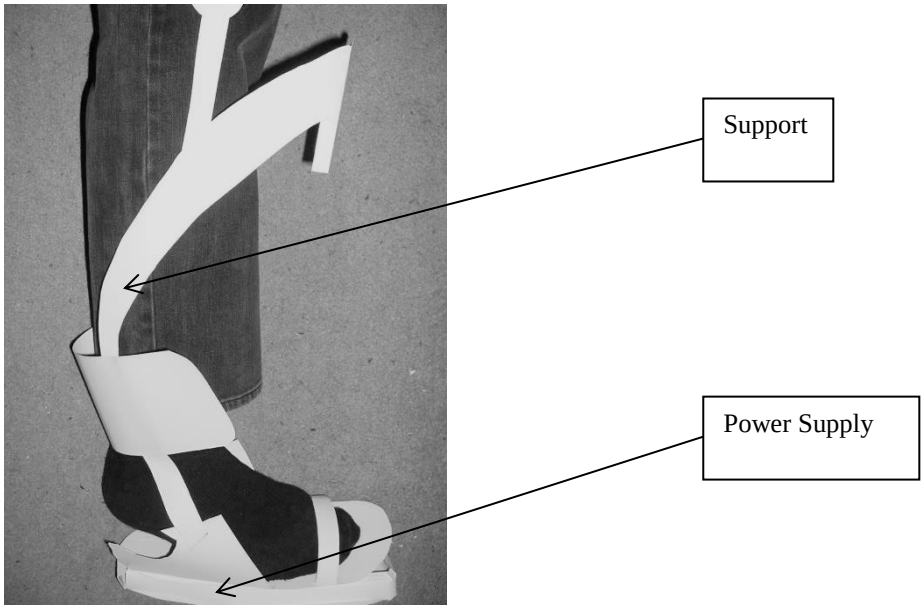
It was suggested that an alternative to developing an exoskeleton device was to design a rollator. The exoskeleton fits the outline of the person's body, which can make it expensive to build only suitable for use by the user. The rollator consists of an upright device with wheels at the bottom, which the user can hold and walk with. Wires connect from the device to electrodes on the patient's skin, which activate the muscles and allow the person to walk. The system was controlled using switches, which resembled bicycle brakes, located on the handles of the device.

There were many advantages identified with using a rollator. It was much easier for users to get into the correct position to use the device. Rather than climbing into the exoskeleton, the rollator only required the user pull them up in front of the device. The rollator did not need to fit the specific body shape of each individual user, people of different sizes could use the

same device and only require a small amount of adjustment so the device reached the correct height for the user to reach it.

A 3-dimensional model was built to reflect the voice of the intended user. This model was comfortable, small, user friendly and unobtrusive. A 3-dimensional model was created to reflect the perspective of the biological scientist. This model was the bare minimum needed for the device to function, unobtrusive, allowed the user to maintain their stride length and encouraged the user to use a healthy gait. Figure 13(a) displays the 3-dimensional model to reflect the voice of the intended user. Figure 13(b) displays the 3-dimensional model to reflect the voice of the biological scientist.

(a)



(b)

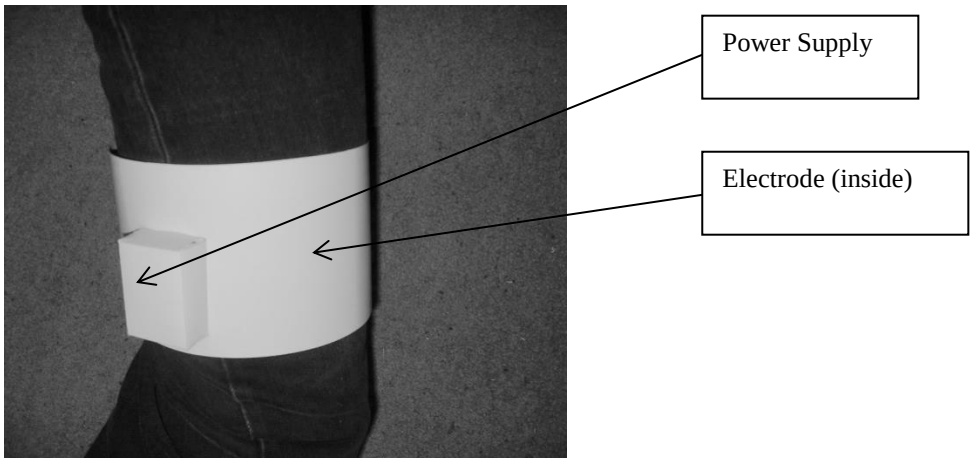


Fig. 13. 3-dimensional models for new FES devices. (a) Model to reflect voice of the consumer. (b) Model to reflect voice of the scientist.

The industry partners also examined the model that reflects the voice of the target user (Fig. 13 (a)). It was considered difficult to determine how the device would be linked to the electrodes on the surface of the skin. It was suggested that the device would be linked to the electrode through special clothes, wires that go through holes in the clothes or wires that go underneath the bottom of the clothes and up the inside. One of the positive aspects of the device was that it did not look like a medical device and it was thought that this might make it more appealing to patients.

The industry partners also inspected the model designed to reflect the opinions of the scientist (Fig. 13 (b)). This design was complimented on for being simple and using a less restrictive design.

A number of considerations were also suggested for the final design. The device needs to be able to allow the user to return to the wheelchair if they become fatigued or if the battery runs out. This would prevent the user becoming stranded when using the device and they would be able to return to a more familiar environment. The technology also needs to be fairly simple to use. The user can be wary of using equipment that is too complicated to master and they may become intimidated by the device.

A number of designs were developed during the second workshop session. The industry partners were able to provide feedback on the efficiency and feasibility of these designs.

One design utilised a technology called "Armour Batteries". This design used a series of connected batteries built into the exoskeleton that power the device. Another design consisted of a wheeled emergency seat that was able to move around while the user sat on it. The design used accelerometers and gyro technology to help the user maintain balance by inhibiting the ability of the device to severely change direction. The industry experts remarked that a number of problems were associated with using gyro technology. Another design used electronics that fitted around the user's fingers to control the movements of an exoskeleton.

One design consisted of a wheelchair that could be folded up and worn as a backpack. The design also incorporated a power pack into the wheel. Another design consisted of a jointed device that fitted around the user's leg to allow bending. This design was created to be more functional for the user, rather than forcing the user to imitate normal walking.

A design was created that consisted of a belt with pegs attached. The pegs would unfold during falling and support the rear and side of the user. Alternatively, the pegs would unfold to the rear of the user and special elastic material would stretch the legs to prevent the user falling sideways. The device would be powered using wireless charging technology. It was suggested by the industry partners that the design would be more suitable for users with more upper body strength.

One of the designs used air bags that ran down the legs of the user and would inflate during falling to keep the user upright. Another design consisted of a wheelchair that could be attached to a series of cables to allow the user to transfer from the wheelchair to a frame that allowed walking. The design also allowed the seat of the wheelchair to become a harness for the frame. The industry experts were complimentary about the design as it considered how the user would be able to transfer from a comfortable position to a stance suitable for walking. One design consisted of a walking stick with hidden appendages that spread out during falling to support the user. These appendages could be attached to wheels to make walking easier.

A design was produced that fitted among the lower leg. The design would detect the user's fatigue and drop the user into a position where the balance would be centred in the knees. Dropping the user's position would allow them to rest and prevent the user from falling. A lower leg exoskeleton would be used to allow the user to return to a standing position. Alternatively, the design could use functional electrical stimulation to cause the knee to drop forward and recover standing position after the user has rested. The industry partners were enthusiastic about the design.

The industry experts responded positively to the designs. The industry partners were enthusiastic about the safety measures designed during the workshop. The safety measures would need to be altered to allow the user to return from an upright position to a comfortable position.

The next stage of the design would be to produce a hybrid design. The three designs to reflect the voice of the engineer, voice of the consumer and voice of the scientist would be amalgamated to form a hybrid design. This task would be completed by arranging a workshop which included consumers, scientists and designers to produce designs that reflected the needs of each group. The most effective design would be used as the final design for the functional electrical stimulation device.

5 Conclusions

Part of the stated aims for the project was to research functional electrical stimulation and scope the range of alternative methods to treat spinal injury. The basic mechanism of functional electrical stimulation was investigated and a range of benefits of using the device were discovered. A number of problems associated with current designs for functional electrical stimulation devices were found during a search of the literature and suggested by industry experts. These limitations were used as a starting point to design more suitable devices.

A range of alternative equipment to help spinal injury sufferers to walk was found during the project. Each individual device was placed into a category with similar machines that performed the same function. The mechanisms that allowed these devices to help users were investigated, along with any added components that allowed the machines to perform extra functions. The devices examined during the literature review also included products that used functional electrical stimulation. The positive and negative aspects of each of the technology was investigated and used to inform the final design.

A number of designs were also created during the project. All of the designed devices used functional electrical stimulation technology. Some of the designs solved particular problems associated with electrical stimulation technology that was suggested during discussions with industry experts and reviewing relevant literature. Separate designs were also produced that reflected the views of a selection of people familiar with similar devices (these were engineers, scientists and target users). Other designs were formed by designers who were inspired to make designs after being introduced to functional electrical stimulation.

A number of the designs were transferred onto computer-aided design software. A 3-dimensional simulated model of one of the designs was produced using the design software. Low level prototypes were also produced of some of the designs.

The designs were presented to representatives from industry as part of a validation process. The experts commented on the feasibility and effectiveness of the designed devices. The experts also provided feedback on the positive aspects of the designs and aspects that could be improved.

A number of actions can be performed in the short-term. These actions include developing a hybrid design and validating the design created during the project.

The next stage of the project would be to produce a hybrid design. This can be accomplished by arranging a meeting between target users, scientists and engineers to produce designs that reflect their individual needs.

A number of features would have to be incorporated into the design. The device would need to be comfortable, ergonomic, provide security, provide a natural gait and have a safety feature. The device would also need to keep the ankle and hip joints stiff and the knees and hips in the correct position to allow a natural standing position. The device would also need to allow the ankle joint some degree of flexibility during movement to encourage the ankle joint to strengthen. The device would also need to have a safety feature added to the design that would be activated when the device ran out of power or became damaged. The safety feature would ensure the user was not hurt if the device became unable to function. The design produced by the scientists (Fig. 11 (b)) appeared to provide comfort, was ergonomic and allowed a normal gait. The design also presented a problem, it provided very little security. The device could be improved if it was used with a wheeled structure, which the user could hold onto as they walked and they could to support themselves if the device cases to function.

The validation of the designs could be improved by gathering feedback from experts and target consumers. The designs could be reviewed using a workshop that used scientists, potential users and engineers to express their opinions on the feasibility of the designs and improvements that can be made.

The designs could also be validated using the opinions of potential users. This can be accomplished by producing a questionnaire, designed to examine the responder's views on the comfort and safety of the device. This questionnaire would be presented to people who use functional electrical stimulation devices and producers of equipment that help people to walk. The results of this questionnaire would be analysed to produce a predicted response of the target market to the production of the designed device.

The responses from the questionnaire and consultations with experts would be used to refine the designs to produce an improved design that would satisfy each expert's specific needs.

This design would be hybrid (as it would be a combination of the designs produced by the target users, scientists and engineers) and would have an expectant value in the market.

Actions that can be completed in the long-term include developing a prototype of the hybrid design and validating the design.

The hybrid design would be altered to improve the device according to the results of the validation process. A 3-dimensional prototype of the design would be produced that allowed user's to practice walking with the model and could be used to demonstrate walking with the device.

This design can be validated by allowing the target users to practice using the device. The user would be instructed on how the device functions and would be allowed to use the device for a short period of time. The user would be questioned on how comfortable the device was, how secure they felt using the device and if they had any other ideas that could improve the design.

The design can also be validated using the opinions of medical professionals. The device would be demonstrated to the medical experts by someone using the device and walking with the device. The experts would then be asked if the device produced the desired walking motions and if they could foresee any health problems associated with regular use.

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Appendices

Appendix A – Glossary

Adhesion	-	Joining of structures with a fibrous band of scar tissue
Aetiology	-	Cause of a disease
Aortic atherosclerosis	-	Obstruction of aorta by deposits of fatty material on the inner wall
Apnea	-	Pause in breathing
Arterial pressure	-	Pressure of blood within the arteries
Astrogliosis	-	Death of astrocytes
Atrophy	-	Degeneration of a part of the body
Axon	-	Long part of a nerve cell that takes an impulse from the cell body to the end organ
Axonotmesis	-	Severe nerve injury with preservation of nerve sheath
Axoplasmic flow	-	Flow of molecules along the plasma of the axon
Basel ganglia	-	Small masses of nerve tissue within the brain that connect the cerebrum with other parts of the nervous system to regulate voluntary movements
Biomechanics	-	Application of mechanical theory to biological systems and the properties of biological material
Bradycardia	-	Decrease in heart rate
Bradykninins	-	Peptide that stimulates skin pain receptors during inflammation
Brainstem	-	Part of the brain that contains the medulla oblongata, midbrain and pons and is connected to the spinal cord
Calcify	-	Process where calcium salts are deposited in organic tissue and harden it
Calmodulin	-	Protein that regulates a number of cellular activities
Capillary pressure	-	Pressure of blood within the capillary
Cartilage	-	A firm, flexible tissue made up of glycosaminoglycan, chondrocytes, collagenuous fibres and elastic fibres and is used to connect bones
Catacholamines	-	A type of amine that can act as a hormone or a neurotransmitter
Cerebellum	-	Part of the brain concerned with muscle coordination and regulation, maintenance of muscle tone and balance, made up of white matter surrounded by grey

		matter
Cerebral cortex	-	Layer of grey matter that envelopes the cerebellum and is responsible for the control and integration of voluntary movement, senses and thought processes
Chiari Type 2	-	Abnormal brain development caused by defects in the neural tube and pressure from hydrocephalus
Central nervous system	-	The part of the nervous system that coordinates neural functions, comprises the brain and spinal cord
Cervical region	-	Vertebrae of the neck, supports the head and allows the spine to move the head
Choreoathetoid cerebral palsy	-	Specific form of cerebral palsy that presents with abnormal muscle tone and inability to control muscles
Chromatolysis	-	Breakdown of Nissl's granules, substances found in the protoplasm of nerve cells
Cognitive difficulties	-	Difficulties with thinking, learning or judging
Collagen	-	An insoluble fibrous protein
Connective tissue layers	-	A layer of tissue containing cells, fibres and intercellular material and is involved in support, immunity and repair
Corticospinal tract	-	A large bundle of fibres that lead from the precentral motor and premotor area to the medulla oblongata
Cystic lesions	-	Gap in tissue structure lined by an epithelium
Cytokines	-	A soluble chemical released by lymphoid cells to signal other lymphoid cells
Degeneration	-	Changes in cells, tissues or organs that impair function and breakdown the affected part
Demyelination	-	The removal of the myelin sheath from a nerve cell
Diplegia	-	Upper limb function better than lower limb function despite asymmetry
Dorsal root ganglion	-	A mass of nervous tissue containing cell bodies and synapses enclosed within a sheath of connective tissue and located on the dorsal side of the spinal cord
Dura mater	-	The outermost of the meninges that surround the central nervous system and protects the other meninges
Dyskinetic	-	Nerve damage that causes involuntary movements
Dysphagia	-	Difficulty swallowing
Dystonia	-	Abnormal muscle tone
Ectopic	-	An event that occurs at an incorrect location
Encephalopathy	-	Any degenerative disease of the brain
Endoneurium	-	Delicate bands of connective tissue that surrounds nerve fibres
Endothelial cell wall	-	A single layer of thin cells that line the inner surface of vessels and organs
End plate	-	The area of the plasma membrane of a muscle cell that lies beneath a motor nerve ending at a neuromuscular junction and releases neurotransmitters
Enkephalins	-	Natural opiate pentapeptides
Ergometer	-	Device used to measure muscle power
Extracellular area	-	Area outside the cells
Extraneural	-	Outside the neuron

Fascia	-	A sheet of fibrous connective tissue located beneath the skin
Fascicular pressure	-	Pressure of the fascia
Fibroblasts	-	Cell that secretes fibres in the intracellular substance of connective tissue
Fibrosis	-	Formation of fibrous tissue, fibroid or fibrous degeneration
Filopodia	-	Long projection of the membrane
Fluid pressure	-	Pressure of the fluid
Glial scars	-	Damaged cells of the nervous system that support the neurons
Hemiplagia	-	Paralysis of one side of the body
Heterogeneous	-	Not all the same
Histamine	-	Substance released during allergic reactions which dilates small blood vessels and makes them more permeable
Hydrocephalus	-	Dilation of the cerebral ventricle that causes an accumulation of cerebrospinal fluid within the skull
Hyperalgesia	-	Increased sensitivity to pain
Hyperirritability	-	Increased sensitivity to stimulus
Hypomyelination	-	Decreased production of myelin sheath
Hypotension	-	Low blood pressure
Hypotonic	-	Decreased tone or pressure
Hypoxia	-	Decreased oxygen in tissues
Idiopathic scoliosis	-	Self-originated congenital lateral curvature of the spine
Inflammation	-	Defensive reaction of cells to injury, irritation or infection
Inflammatory cascade	-	A series of physiologic processes that results in inflammation
Innervation	-	The supply of nerve fibres to and from an organ
Intervertebral disc	-	Discs of cartilage that separate the bones of the vertebral column and allow flexibility and shock absorbance
Intervertebral foramina	-	An opening within the vertebrae
Intracranial pressure	-	The pressure exerted on the brain by the cerebrospinal fluid
Intraneural	-	Within the neuron
Ion channel	-	Protein which forms a water filled tunnel through the cell membrane to allow ions to pass in and out of the cell
Ischemia	-	Low oxygen state caused by low blood flow that leads to hypoxia
Lesion	-	Gap in tissue structure
Leukotrienes	-	Compounds synthesised from arachidonic acid and attract immune cells, increase permeability of small blood vessels and cause vasoconstriction
Lower motor neurone	-	Neurone located within the brainstem that connects central nervous system to nearby muscles
Lumbar region	-	Vertebrae in the lower back that allow attachment to back muscles

Macrophage	-	Large immune cell that ingests pathogens
Mechanoreceptor	-	Receptor that responds to mechanical stimuli
Mechanosensitivity	-	Sensitivity to touch and pain
Melatonin	-	Hormone derived from serotonin that regulates changes over time and controls pigmentation
Microgliosis	-	Death of microglia cells
Microtubules	-	Tubular structures within cells that help cells maintain shape and allow intracellular materials and organelles
Mitosis	-	Nuclear division that results in identical daughter cells
Muscle spindles	-	Stretch receptor within vertebrae muscles and allow maintenance of posture and movement
Muscular contraction	-	Process that causes shortening and tension of muscle tissue
Musculoskeletal	-	Muscle, bone and cartilage
Myelin sheath	-	Layer of fatty material that surrounds and electrically insulates axon to allow rapid transmission of impulses
Myelopathy	-	Destruction of spinal cord tissue
Necrosis	-	Death of cells by toxic substances
Neonatal	-	First four weeks after birth
Nerve fibres	-	The axon of a neuron and the associated tissue
Nervi nervorum	-	Sensory nerve fibres within the epineurium
Neural filaments	-	Type of filament present in axon that act as part of cytoskeleton
Neural tube	-	Hollow tube of tissue within the embryo that develops into the brain and spinal cord
Neurulation	-	Formation of the neural tube by closure of neural plate
Neurite-promoting factor	-	Chemical that promotes growth of neurite
Neurocentral synchondrosis	-	A joint in between articulating bone where cartilage transformed into bone
Neurogenic	-	Lesion within brain, spinal cord or peripheral nerves
Neuromotor impairment	-	Hindrance in ability of nerve cells to cause muscular contraction
Neurons	-	Elongated cell that allows conduction of impulses
Neuropeptides	-	Molecules made up of two or more amino acids that influence neuron activity
Neurophysiology	-	Physiology of the nervous system
Neuropraxia	-	Impaired conduction without axonal damage
Neurotmesis	-	Severe injury with nerve severance and anaesthesia in nerve distribution
Neurotransmitters	-	Chemical that mediates transmission of a nerve impulse across a synapse or neuromuscular junction
Neurotrophic factor	-	Regulates neuron development
Nociceptive sensory endings	-	Nerve endings that are involved in pain sensing
Non-progressive damage	-	Damage that does not become worse over time
Occlusion	-	State of being closed
Oedema	-	Accumulation of tissue fluid in body tissues, leading to swelling
Oligodendrocytes	-	Cells of the nervous system which myelinate central nervous system axon
Oligodendroglial progenitors	-	Cell that divides into oligodendrocytes

Opisthotonos	-	A severe form of spasm that causes the back to arch, head to lean backwards and heels to flex
Ossification	-	Formation of bone by osteoblasts depositing bone onto connective tissue
Osteoporosis	-	Weakened bones
Paraspinal muscle	-	Muscles beside the spinal column
Paresthesia	-	Abnormal neurological sensations, such as numbness, tingling, burning and pricking
Paroxysmal	-	Recurring paroxysms, spasms or seizures
Pathology	-	The changes to the body caused by disease
Pathomechanic	-	Mechanical effects of disease
Pathophysiology	-	Abnormal body functions or functions changed by disease
Peptides	-	Compounds containing two or more amino acids linked by a peptide bond
Percutaneous electrode	-	Electrode inserted into the skin
Perineural compartment	-	Compartment that surrounds the neurons
Perineurium	-	Sheath of connective tissue that surrounds a bundle of nerve fibres
Peripheral nerves	-	Nerves that connect the central nervous system with the receptors and effectors
Periventricular leukomalacia	-	Cranial abnormalities that became cystic
Phagocytosis	-	Process where pathogens are surrounded by a membrane and broken down using chemicals
Physiology	-	The vital functions performed by the body
Posterior vertebral arch	-	The posterior projection from the body of the vertebrae that encloses the vertebral foramen
Posterior	-	The rear of the body
Potentiometer	-	Device used to measure electromotive force or potential difference by comparison with known force
Prostaglandins	-	Compounds derived from essential fatty acids and affect muscle contraction, blood circulation and inflammation
Proteoglycans	-	A polysaccharide chain linked to a protein subunit located in connective tissue
Protrusion	-	State of thrust forward
Proximal segment	-	Part of the organ nearest attachment
Quadriplegia	-	Paralysed in all four limbs
Rectus capitis posterior minor muscle	-	One of the muscles located beneath the occipital bone, innervated by the suboccipital nerve and allows proprioception
Regeneration	-	Growth of new tissue to replace damaged or lost tissue
Reinnervation	-	Regrowth of damaged nerve cells
Remyelination	-	Regrowth of damaged myelin sheath
Sacroiliac joints	-	Joint between ilium and sacrum to attach spinal cord to pelvis
Schwann cell	-	Cell that forms the myelin sheath of axons
Sclerosis	-	Hardening due to disease or inflammation, particularly in the nerves or blood vessels

Serotonin	-	Compound that mediates inflammation and allergic reaction by influencing blood vessel diameter, also functions as neurotransmitter
Somatosensory complex	-	System that uses neural receptors to allow the body to sense pressure, temperature, position and pain
Spastic	-	Affected by spasms or presents with stiff muscles and awkward movements
Spinal cord	-	Central nervous system below brain and within vertebral column, containing a hollow core of grey matter, cavity containing cerebrospinal fluid and white matter containing nerves
Stimuli	-	Changes inside and outside of body that provokes a response
Subchondral bone	-	Bone below the cartilage of the ribs
Substance P	-	A neuropeptide that mediates the parasympathetic nervous system by stimulating gut contractions, saliva production and dilation of blood vessels
Syrinx	-	Organ that allows birds to produce sounds using vibrating membranes
Temporomandibular joint	-	Joint attached to jaws
Thalamus	-	Part of the brain that relays sensory information to cerebral cortex and translate impulses into sensations
Thrombophilia	-	Disorder that increases blood clotting
Transforaminal ligaments	-	A fibrous band of connective tissue which stretches across the intervertebral foramina
Traumatic Schmorl's node formation	-	Formation of protrusions of the cartilage of the intervertebral disc caused by a trauma
Tunnel pressure	-	Pressure of blood within the small blood vessels that lead to the heart
Undulations	-	Wavy in appearance or wave-like movements
Vascular system	-	A network of vessels to allow circulation of fluids around the body
Vascular perfusion	-	Passage of liquid through the vascular system
Vasoactive intestinal peptides	-	A peptide hormone that prepares the pancreas and small intestine for food, also functions as a neurotransmitter
Vasoactivity	-	Activity of the vascular system
Venous pressure	-	Pressure of blood within the veins
Ventriculomegaly	-	Enlargement of the ventricles
Vertebral column	-	A flexible column of bone that provides spinal support and attachment to muscles, ribs and pelvis
Wallerian degeneration	-	Degeneration of nerve cells caused by division
White matter	-	Part of the central nervous system that consists of nerve fibres enclosed within white myelin sheath, allows transmission of nerve impulses to brain and to end organs
Zygapophysial joints	-	Joints between small flat projections on the vertebral column

Appendix B – Gantt Chart

Task	Month											
	1	2	3	4	5	6	7	8	9	10	11	12
Literature Review												
Discuss Project with Industry Partner												
Compile Product Matrix												
Produce Designs												
Transfer Designs onto CAD Software												
Produce 3-D Designs												
Produce 3-D Model of Design												
Discuss Designs with Industry Partner												
Workshop to Validate Design Ideas												
Write up												

Appendix C – Additional Information

2.1 Causes of Paralysis

2.1.1 Spinal Injury

There is a wide range of ways in which the spine can become damaged and limit in function. For example, it was calculated that between 15% and 40% of cases of chronic lower back pain was related to the adhesion or degeneration of zygapophysial joints [4]. The problems associated with the zygapophysial joints were considered to be caused by loss of signal potential or real tissue damage of the nociceptive (or free nerve endings) sensory endings.

Intervertebral disc degeneration was also identified as a cause of spinal damage. The intervertebral discs are discs, made of cartilage, that separate the bones of the spinal column and allow flexibility and can absorb shocks. Degeneration of the discs can be caused by a loss of fluid pressure, disruption or breakdown of collagen and proteoglycans, or sclerosis of the cartilaginous end plate and the adjacent subchondral bone. Degeneration of the discs also occurs as part of the aging process. Disc degeneration can also be initiated and accelerated by certain diseases, such as traumatic Schmorl's node formation, advanced aortic atherosclerosis and nicotine consumption. Many people suffer back pain caused by degeneration of the intervertebral discs.

Another effect of disc degeneration is a change in innervation of the intervertebral discs. Innervation increased around intervertebral discs. Innervation is the system of nerve fibres to and from an organ. Sensory fibres, conducting nociception, increase innervation around degenerated discs, which increases their susceptibility to pain.

Spinal column damage can also be caused by connective tissue attachments to the spinal dura mater. The dura mater is a membrane that surrounds and protects the central nervous system and is situated close to the skull. An increase in tension of the cervical paraspinal muscles may cause traction between the rectus capitis posterior minor muscle and the dura mater. This may increase the dura tension and cause headaches [7].

Evidence has suggested that the connective tissue between the rectus capitis posterior minor muscle and the dura mater can tear during trauma to the cervical region of the spine [4]. This incident can cause the dura mater to buckle into the cervical segments of the spinal cord, which can result in chronic neck pain, disturbed balance, headaches and signs and symptoms

of cervical myelopathy. Traction can also increase in the dura mater if intervertebral disc protrusion affects homologus attachments in the lumbar region of the spine.

Idiopathic scoliosis has been identified as a disease that causes damage to the spinal column. A genetic component, along with secondary factors, was a likely cause of the disease [65]. The disease causes a decrease in melatonin production, leading to an increase of circulating levels of the hormone calmodulin. Melatonin is involved in the dark-light cycle of the organism's environment, regulating certain diurnal and seasonal changes to the body and controls pigmentation changes [1]. Calmodulin is a molecule involved in regulating numerous cellular activities. The combination of low melatonin levels and high calmodulin levels results in numerous physiological changes to the body, such as changes to skeletal muscle and connective tissue, distortion of the ribs, changes in bone density, decrease in height of the posterior vertebral arch, asymmetry of the neurocentral synchondrosis, and the formation of the syrinx and other neuroanatomical abnormalities in the spinal cord. Changes in dental occlusion and temporomandibular joint disturbance could cause a tilt in the first cervical vertebra, leading to a change in the alignment of the adjacent vertebra and destabilising the vertical alignment of the spine [66].

Transforaminal ligaments can form on the intervertebral foramina (opening in the vertebrate). These ligaments can become sturdy and can calcify (take up calcium and harden) [4]. The presence of the transforaminal ligaments can cause low back pain, nerve root entrapment and neurological symptoms in the region.

Acquired accessory sacroiliac joints can form within the posterior (fibrous) portion of the joint. These sacroiliac joints occur frequently, although they are more common in obese and older people, and are associated with periodic low back pain and signs of degeneration [8].

Muscle spindles (specialised cells, present in vertebrate muscles, which are sensitive to mechanical stress) were involved in normal reflex activity and lumbar spine repositioning to ensure the pelvis and lumbar spine remain in correct position [9]. Individuals suffering from low back pain have an impaired ability to reposition the lumbar spine; this effect can be reduced in the presence of vibration stimulus. In healthy individuals, the ability of the lumbar spine to reposition can become inhibited if vibration stimulus was applied.

2.1.2 Nerve Injury and Laceration

Nerve injury can be split into three categories: neuropraxia, axonotmesis, & neurotmesis. Neuropraxia occurred when the nerve undergoes focal demyelination (removal of the myelin sheath), without the connective tissue of the nerve and axon becoming damaged. Neuropraxia was mainly caused by either changes to the ion channels present on the nerve cells or a localised ischemic event, which result in a loss of the ability of the nerve to conduct electrical impulses. Axonotmesis resulted in damage to the axon and the surrounding myelin sheath, without affecting the surrounding connective tissue layers (called the endoneurium and perineurium). Neurotmesis resulted in partial or complete disruption of the peripheral nerves and can lead to damage to all the layers of connective tissue. Axonotmesis and neurotmesis present with a larger loss of motor and sensory functions, which can be partially or completely permanent [5].

To recover from axonotmesis and neurotmesis, the nerves undergo Wallerian degeneration and regeneration. Degeneration began within hours of the injury, starting with fragmentation of the axon and myelin sheath. Within the next four days, the axon loses continuity and the nerve loses its conductivity. Between the first week and several months, the Schwann cells, using nearby macrophages, causes phagocytosis of the axon and myelin sheath debris. In the proximal segment of the nerve fibre, degeneration spreads to nearby myelinated regions, but severe injury can cause degeneration to affect the nerve cell. The nerve also undergoes chromatolysis (breakdown of the chromosome) to prepare for the regeneration of the axon.

In the distal segment of the nerve fibre, degeneration leads to the removal of the myelin sheath and axon from the entire segment. Schwann cells undergo mitosis (cell division) and form tubes that express surface molecules that guide the regenerating axon. The Schwann cells are surrounded by perineurium and endoneurium fibroblasts, which rebuild the connective tissue envelope of the peripheral nerves.

After Wallerian degeneration has ended, the nerve undergoes a process of regeneration. At the tip of a regenerating axon is a growth cone, a specialised mobile filopodia that enables the axon to explore its immediate environment. The presence of neurotrophic factors and neurite-promoting factors are the primary factors responsible for the development of distal axons [67]. The neurotrophic factors (such as nerve growth factor) promote survival and growth of the developing axon and may help determine the axon's endoneural tube and specificity of reinnervation of the end organ. The neurite-promoting factors help accelerate the regeneration

and progression of the axon. Other factors (such as adhesion and cross reinnervation) can also affect axon regeneration. Reinnervation specificity restores motor function, with a specific modality that determines the function of the nerve. Remyelination occurs along the regenerating axon at the same time.

The promotion of axonal recovery and the selectivity of end organ reinnervation were important to fully recover nerve function [10]. Poor functional recover was caused by inability of all the axons to undergo regeneration, misdirection of the axon and reinnervation of inappropriate end organs and permanent changes to the central nervous system within the motor neuron and the somatosensory complex.

2.1.3 Nerve Compressions

Nerve compression can be split into three categories. The first category refers to a nerve that was mildly compressed, but did not result in weakness of the muscle connected to the nerve. The second category refers to a nerve that experienced enough compression that the innervated muscle weakened without becoming atrophied. The third category refers to a nerve that became compressed to a degree that caused the muscle to become weakened and atrophied and led to paralysis [5].

While the pathophysiology (the physiology of the disease) of most acute nerve injuries is caused by damage to the axon, the pathology of nerve compression is not related to axonal damage. Changes to the peripheral nerves and accompanying neurons were caused by compression and sheer forces and changes to the Schwann cell. The vascular system maintains vascular perfusion (circulation of the blood) and physiology. The vascular system relies on the arterial pressure to be higher than the capillary pressure, which has to be larger than the fascicular pressure, which needs to be more than the venous pressure, which has to be bigger than the tunnel pressure, to circulate blood around the body. The presence of mechanical forces (such as compression and sheer forces) can change the pressures listed above and (if they cause the pressure to become lower than the pressure in the adjacent area) can affect circulation.

If the change in pressure prevents normal circulation, blood can collect in the blood vessels and lead to axonal hypoxia (axon takes up less oxygen which can damage it). Continued external pressure can cause a breakdown in the endothelial cell wall of the blood vessel and

result in perineural compartment oedema (leakage of blood components into the bundle of fascia surrounding nerve cells). The presence of oedema can increase the pressure within the nerve and cause more compression, which can lead to intraneural fibrosis.

Compression of the nerves can also affect the Schwann cell. The Schwann cell can cause demyelination along the nerve, which can affect its ability to conduct impulses. Schwann cells may also proliferate in an attempt at remyelination of the nerve [68].

The peripheral nerve contains undulations throughout the layers of connective tissue and axon, which allows it to cope with strain and flex and relax when the body is in motion [5]. After intraneural fibrosis occurs, the nerve has a reduced ability to react to compression. The increase in endoneural compartment pressure causes an increase in the diameter of the perineural compartment, which forms an underlying strain on the perineurium. The strain on the perineurium affects its strain capabilities and the peripheral nerve as a whole. Nerve compression also affects the process of neural excursion.

2.1.4 Neuropathic Pain and Neural Tension Dysfunction

Peripheral nerve has the ability to tolerate motion to the extremities. The loss of this ability can lead to the development of neuropathic pain and neural tension dysfunction, which can result in loss of extremity function [5]. These effects are caused by alterations of the neurophysiology of the body.

The most common feature of neural tension dysfunction is neuropathic pain. While the aetiology of neuropathic pain is largely unknown, it is thought that abnormal impulse generating sites play a large role. These sites are a source of ecotopic stimulus (stimulus from outside the nerve) and form near areas that have experienced a change in ion channel function or number (usually at a site of demyelination). This alteration can cause microneuromas to form.

Neuropathic pain may be caused by impulses generating in demyelinated, damaged and regenerating afferent fibres. The abnormal impulse generating sites can be stimulated by a variety of different stimuli, such as temperature, presence of cytokines, presence of catacholamines, metabolic stimuli and mechanical stimuli. Eventually, abnormal impulse generating sites can change the function of dorsal root ganglion and neurons in the central

nervous system (this is known as central sensitisation). Pain caused by abnormal impulse generating sites is also described as dysesthetic pain.

Neuropathic pain can also be caused by nerve trunk pain. Nerve trunk pain was considered to be caused by chemically-mediated increased mechanosensitivity of the neural tissue; this reaction causes an inflammatory cascade to occur within the nerve. With the application of the correct stimuli (either tension or compression), the nociceptive endings in the nervi nevorum (connective tissue of the peripheral nerve) can become more active. The nervi nevorum can cause the release of calcitonin-gene-related peptides and result in an inflammatory cascade within the nerve [5].

Neuropathic pain could also be caused by chemical sensitisation of the peripheral nervous system, which results in increased mechanosensitivity [5]. A variety of neurogenic (neuropeptides) and non-neurogenic chemicals have been suggested as causes. The non-neurogenic chemicals (released from injured connective tissues) include bradykinins, serotonin, histamine, prostaglandins, and leukotrienes. The neurogenic chemicals (released by primary afferent neurons after damage to the peripheral afferent neuron) include substance P, calcitonin-gene-related peptides, vasoactive intestinal peptides, and enkephalins. The release of these chemicals causes neurogenic inflammation that leads to increased mechanosensitivity of the nervous system. The increased mechanosensitivity of the nervous systems results in a number of effects, including neural hyperalgesia and neuropathic pain.

A variety of symptoms are associated with neuropathic pain, which can occur in the presence of stimulus or remain after the particular stimulus is removed. Induced neurogenic inflammation and subsequent increased mechanosensitivity can cause spontaneous pain, which can be felt in another part of the body [11]. Neuropathic pain may be deep (which feels like cramps, aches and throbbing) or superficial (which feels like burning, pinching or stabbing) [12]. Sometimes, the pain is paroxysmal and is described as shooting pain and similar to an electric shock. The pain may also have a delayed response and only felt after repeated stimulation.

A number of bizarre symptoms may be experienced by sufferers of neuropathic pain. The pain may radiate from a focal point and run “along a track”, or it may be felt in other areas as clusters, or clumps, of pain. These strange effects have been suggested as caused by spontaneous ectopic discharges or lowered threshold mechanoreceptor function [5].

Neural tension dysfunction can cause hyperirritability of the peripheral nervous system and the interfacing tissues through a number of physiological effects. External compression or harmful tension can cause oedema or ischemia and inhibit the vascular neurodynamics. Neural biomechanics (strain, excursion and compression processes) can be affected by the formation of fibrosis. Intraneural fibrosis (fibrosis within the nerve) can harm the tortuous course of the nerve or its undulations, inhibiting the motion of the nerve and its ability to unfold. Extraneural fibrosis (fibrosis outside the nerve) can inhibit the movement of the nerve along the nerve bed and between the interfacing tissues, resulting in mechanical interference. The presence of fibrosis limits how the nerve prevents strain and its movement, which can cause pain and adaptive shortening of the nerve (which can affect movement of the joints and the function of the extremities).

The presence of neural tension dysfunction can interfere with the axoplasmic flow of the nerve. Inhibiting axoplasmic flow can damage axon viability by limiting the transport of neural filaments, microtubules and neurotransmitters along the axon to the terminal ending and returning metabolic by-products to the cell. This effect can produce significant damage to the physiology and function of the nerve.

The inhibition of axoplasmic flow can increase the nerve's vulnerability throughout the upper extremity, in interfacing tissues or at relatively fixed points where they branch or pass through the fascia (which increases the stiffness of the nerve, which also reduces the nerve's force attenuation capabilities).

The effects of neural tension dysfunction can be either pathophysiologic (neurogenic symptoms, such as pain and parestheia) or pathomechanic (alterations in the neural mechanics that can limit the motion of the upper extremity).

2.1.5 Cerebral Palsy

Cerebral palsy was a group of permanent disorders that affects the development of posture and movement, which cause activity limitation and are attributed to non-progressive damage that occurred in the developing foetal or infant brain [6]. The primary symptom of cerebral palsy is motor dysfunction, but other symptoms can also occur, such as epilepsy, secondary musculoskeletal problems and disturbances to sensation, perception, cognition, communication and behaviour. Cerebral palsy can be described as spastic (hemiplegia,

diplegia or quadriplegia), dyskinetic (choreoathetoid or dystonia), hypotonic or mixed (Table 1).

Table 1, a table to display the symptoms experienced by an infant suffering from cerebral palsy.

Age of Infant	Symptoms of Cerebral Palsy
Less than 2 months	Delayed motor milestones, toe walking, persistent fisting, increased rate of growth of head circumference, seizures, irritability, poor suck, early development of handedness and scissoring
Over 2 months	Poor head control, stiff legs and scissoring
Over 6 months	Poor head control, unable to sit unsupported and prefer to use only one extremity
Over 10 months	Crawl using one hand and foot while dragging the other hand and foot and unable to stand without support
Over 12 months	Unable to crawl or stand without support
Over 24 months	Unable to walk

Cerebral palsy was the most common cause of physical impairment in children [69]. Cerebral palsy is caused by non-progressive pathology in the infant brain that can cause early-onset impairment of the neuromotor system. Many patients with cerebral palsy also exhibit symptoms independent of neuromotor impairment, such as cognitive difficulties, metabolic disturbances, epilepsy, speech and language difficulties, primary sensory impairment and behavioural difficulties [13].

The causes of cerebral palsy are heterogeneous and there is no single aetiology that causes the disease. The majority of cases were either caused by inherited malformation of the brain or an injury to the developing brain [69]. It was also found that cerebral palsy was caused by an interaction of genetic and environmental factors. A number of risk factors have also been suggested, including prematurity, maternal infection, inflammation and inflammatory response, thrombophilia, vasoactivity, sex and neonatal encephalopathy. However, 20% of cases of cerebral palsy presented with no identified cause. It is also unknown what factors were responsible for a patient's resilience or vulnerability to injury.

One of the most important factors that cause cerebral palsy is birth prematurity. Premature babies present with long-term cognitive, motor and behavioural dysfunction and are the largest subgroup of children to develop cerebral palsy.

The most common cause of brain injury in premature babies is known as periventricular leukomalacia. Periventricular leukomalacia resulted from injury to the cerebral white matter and consists of two components, focal and diffuse. The focal part is made up of localised necrosis (uncontrolled cell death) occurring deep within the periventricular white matter, resulting in the loss of all the cellular elements. These necrotic components can be small and then grow into multiple cystic lesions (this is known as cystic periventricular leukomalacia). The necrotic areas can also start small and grow into glial scars (this is known as non-cystic periventricular leukomalacia) [70].

The diffuse aspect of periventricular leukomalacia is associated with astrogliosis and microgliosis and with a decrease in premyelinating oligodendrocytes. The decrease in oligodendrocytes causes an increase in oligodendroglial progenitors. The oligodendroglial progenitors do not have the capability to differentiate into mature myelin-producing cells, leading to the development of hypomyelination with ventriculomegaly. One theory to explain how the oligodendroglial progenitors lack the ability to mature is because they are sensitive to hypoxic-ischaemic insult, which is a confirm feature of premature infants.

Periventricular leukomalacia may also cause neuronal (or axonal) disease. The areas affected by neuronal disease are the cerebral white matter (axons and subplate neurons), thalamus, basel ganglia, cerebral cortex, brainstem and cerebellum [70]. The disease is characterised by a decrease in number of the neuronal structures.

The presence of periventricular leukomalacia causes a variety of symptoms, however, the patient will only exhibit symptoms associated with particular diseases. A number of patients suffering from cystic periventricular leukomalacia present with spastic diplegia (this is muscle stiffness in the legs that can cause walking difficulty). Non-cystic periventricular leukomalacia results in cognitive deficits, without affecting motor reflexes. The effects of neuronal disease depends on what part of the brain is affected and can cause overall intelligence impairments, object working memory deficits, impairment of various executive functions, loss of impulse control and the presence of some characteristics of autistic spectrum disorders.

Postnatal infections and injury to the cerebral white matter that impair development of the corticospinal tract (part of the voluntary motor pathway) are closely associated with cerebral palsy. Systemic illness, rather than the gestational age of the infant at birth, appears to be the main cause of abnormal microstructural brain development in the corticospinal tract [69].

2.1.6 Myelomeningocele

Myelomeningocele is a disease that leads to loss of motor function. Myelomeningocele was caused by defects in the neural tube that results in neurulation failure (failure of the neural tubes to close). Myelomeningocele refers to the development of neural tube defects which cause the protrusion of the meninges and spinal cord [6].

The effects of myelomeningocele were caused by a range of sources, including motor and sensory loss, development of Chiari Type 2 malformations and presence of hydrocephalus. Usually, the loss of sensory and motor function occurs below the site of the lesion in the spinal cord, however, the level and effect of the loss is not the same in each patient. It is difficult to predict the patient's functional abilities based on the site of the lesion and secondary and associated conditions can also affect the patient's functional abilities. A common symptom associated with myelomeningocele is the loss of sensory function in the external genitalia and anus.

The presence of Chiari Type 2 malformations can lead to a range of secondary disorders. Chiari Type 2 malformations can cause displacement of the brainstem and portion of the cerebellum in a downwards direction, this effect can cause spinal cord compression. Spinal cord compression has been linked to a variety of symptoms including dysphagia (difficulty swallowing), choking, hoarseness, a weak cry, spells of holding breath, apnea, bradycardia, disordered breathing during sleep, stiffness in the arms and opisthotonos. Spinal cord compression can also cause older children to develop an unsteady gait with regular falling. Chiari Type 2 malformations were also associated with hydrocephalus that can cause an increase in intracranial pressure.

2.2 Methods of Managing Spinal Injury

2.2.1 Wheelchairs

Wheelchairs have been identified as the optimal solution to a lack of mobility. Wheelchairs can be separated into two categories, manual and automotive. Manual wheelchairs refer to wheelchairs that the user has to move using their own strength. Automotive wheelchairs are wheelchairs that use robotic systems that move the wheelchair [2].

A number of human-machine interfaces were developed to allow the user to control the device. An automotive wheelchair has been developed that was controlled using electroencephalograms (measurements of a brain's electrical activity) [20]. A robotic wheelchair was built that was controlled using signals from eye blinks and brain activity [21].

A number of health problems were also associated with wheelchair users sitting down for long periods of time. These problems include loss of bone mass, development of osteoporosis, development of skin sores and degradation of blood circulation and physiological function [2].

Other studies have also identified problems that develop with wheelchair use. There are methods that improve oxygen uptake by the skin in the pelvic region. It was found that the wheelchair should tilt at an angle of 35^o and a recline angle (angle of the back of the wheelchair) of 100^o to maximise skin perfusion (uptake of oxygen) of the whole of the body. It was also found that skin perfusion in the pelvic region was maximised if the wheelchair tilt was at 25^o with a recline angle of 120^o [32].

The effects of whole-body vibrations on the wheelchair user can be minimised [34]. Whole-body vibrations can cause spinal deformities, herniated discs, chronic low back pain and harmful physiological responses in the central nervous system and cardiovascular system. The whole-body vibrations occur while the wheelchair user is manually propelling the wheelchair. A range of seat cushions were tested to examine their ability to reduce the effect of vibrations on the wheelchair user. It was found that were either made of contoured foam or were composed of an air bladder with a foam base were the most effective at reducing the effect of vibrations on the wheelchair user [34].

Other problems were associated with prolonged wheelchair use. It was claimed that spending time using a wheelchair can cause the development of pressure ulcers (or bedsores). The physical size and shape of the seat of the wheelchair needed to be correct to prevent pressure ulcers occurring [33]. It was also considered that the material of a cushion used with the wheelchair can also affect the development of pressure ulcers.

One of the problems linked to wheelchair use was the ability of the user to learn how to use a wheelchair properly. The main aspects of proper wheelchair use include good mechanical efficiency (a low ratio between external power output and metabolic power) and correct propulsion technique. Mechanical efficiency was improved if the user learnt how to use a

wheelchair on a track or treadmill, rather than a stationary ergometer, because the user mastered how to move their trunk to counter the inertia of the moving wheelchair. The different methods of learning to use a wheelchair had no effect on developing a good propulsion technique; the only difference was that the subjects developed longer push time if they were trained on the ergometer. It was suggested that learning to use a wheelchair on an ergometer (the simplest wheelchair to use) was the most beneficial, as spinal injury patients could develop good propulsion technique in a safe environment; however, the user would have to change devices to learn complex wheelchair tasks and become accustomed to moving with weight and inertia [35].

2.2.2 Parapodium

A parapodium is an orthosis that allows the patient to stand by supporting the chest, buttocks, anterior knee and heel [14] (Fig. 2). The device allows either a swivel or swing-to gait, which determines if the user can use their arms while using the device. The parapodium also allows the patient to sit while the device is in use, which makes it suitable for children to use in a school setting.

Fig. 2 An example of a parapodium device [15]

The parapodium is usually recommended for very young children and they can learn to use it with a walker as they grow older [14]. The parapodium can be replaced by other orthoses as the patient grows older and achieve a better sense of balance, also, the parapodium can be

difficult to remove independently. A number of benefits of standing have been identified, as well as reasons for the patient to avoid standing (Table 2).

Table 2, a table to display the positive effects of standing and associated diseases that can worsen with standing

Positive Effects of Spinal Injury Patients Standing	Diseases Associated with Spinal Injury that can Worsen with Standing
• Positive psychological effect of user being at eye-level to other people, • Stretches the muscles of the lower leg, • Provides pulmonary hygiene, • Promotes the positive effects of weight-bearing, • Enables exercise and strengthening, • Widens the range of movements and balance for the user, • Encourages the patient to achieve ambulation	• Severe osteoporosis, • Heterotrophic ossification which prevents movement of the lower extremity, • Poor joint integrity, • Significant pain, • Impaired hip or knee flexion contractures, • Cardiopulmonary compromise, • Significant scoliosis or kyphosis, • Significant windswept deformity, • Uncontrolled hypotension, • Skin breakdown

Sufferers of spina bifida that are less than two years old can also benefit from parapodium use [73]. The parapodium supports the spine of the user and allows ambulation of the patient. Parapodium can also be used as part of physiotherapy if a patient loses some of their movement skills after craniocerebral injury [74].

An alternative to the parapodium would be to move the user's body using mechanical forces, rather than the user's own muscle power.

2.2.3 Exoskeleton

An exoskeleton is a device that actively helps the user to move (Fig. 3). The exoskeleton is designed to fit around either the user's entire body or part of it. The exoskeleton also uses mechanical systems to move the body. An exoskeleton is different to a parapodium because it uses a mechanical system to move, the legs can move independently of the arms and it allows a more natural mode of walking. Exoskeletons also function using a number of processes, sensing how the user initiates movement, actuation (moving the device), and source of power.

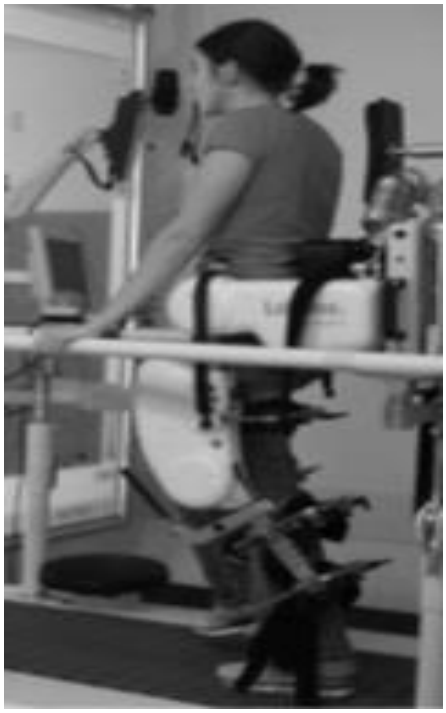
Fig 3. An example of an exoskeleton [16]

One exoskeleton assists movement of the legs. The exoskeleton assisted the hip joint during walking motion. The overall force used to move the hip joint was the same in subjects using the exoskeleton and subjects without movement problems, however, the net muscle moment was less if the subject used the exoskeleton because the device provided some of the torque needed during the movement [36].

The use of the exoskeleton may be beneficial for patients suffering from a number of physiological difficulties. The exoskeleton may be useful to sufferers of hip pain as it reduced the amount of muscular contraction needed to move the hip. The exoskeleton may also limit the development and progression of osteoarthritis in the hip. The exoskeleton could also help sufferers of anterior acetabular labral tears. A majority of the tears were caused by the repeated infliction of strong forces on the anterior hip structures. The strongest forces were identified as hip extension and hip flexion, both of which can be reduced if the patient uses an exoskeleton. The exoskeleton can also help the body provide the necessary hip flexion needed in normal walking, which could benefit people who are unable to produce the normal force needed for hip flexion (such as myopathy patients) [36].

It was also proven that the user benefits if they use an exoskeleton that only assists extension of the ankle. The device used was a bilateral ankle-foot exoskeleton with ankle extension assistance. The user required a small amount of time to learn and master the device, but,

afterwards, the amount of energy the patient used while walking with the device significantly decreased. It was also found that the muscle activity of the ankle increased initially while the user learnt how to use the device, before reducing. This was compared to the reduction from gross muscle activation to a more economical method of muscle activation when the body is learning to perform a task. More time was needed to determine if the metabolic cost and muscle activation decreased further as the subjects used the device more [75].

A number of considerations were identified for designing an exoskeleton for the ankle. An important aspect of exoskeleton development was to identify the principles of human motor adaption and to examine the parameters that influence the rate of motor adaption to the powered assistance. It was found that subjects using an ankle exoskeleton reduced their solus EMG activation by about 36% to walk with the same total ankle moment pattern as unassisted walking. It was also discovered that the use of an ankle exoskeleton had no effect on the dynamics on the knees or hips, despite the device providing around 47% of the moment required during push-off. It was also found that subjects using less powerful devices required less time to adapt to the equipment than subjects using more powerful exoskeletons [76].

An exoskeleton was created to assist the movement of the arms. The device used electromyogram (EMG) on the surface of the skin (specifically the shoulder and elbow) to signal how the user intends to move their arm [37]. The device was also controlled using a force sensor-based controller on the wrist, which was primarily activated when the signals from the muscles were low. An obstacle avoidance controller was attached to the EMG to prevent the exoskeleton colliding with the user's own wheelchair. The rest of the exoskeleton consisted of a shoulder motion part and an elbow motion support part mounted on a wheelchair. The technology was designed to be light, safe, comfortable and easy to maintain.

A number of exoskeleton devices have been developed for the upper limbs. An early rehabilitation robot was the end-effector robot. The end-effector robot holds the patient's arm and generates force at an interface located at the end of a jointed tube. The device is simple, easy to build and can be easily adjusted to fit different people, however, it can be difficult for the device to determine the posture of the arm, the joints of the end-effector can move independent of the user's wishes and the robot can perform a limited range of motions. The end-effector robots were found to improve the motion of the arms of the patient, which

encouraged the improvement of the device and development of an exoskeleton using similar technology [77].

An important aspect of exoskeleton design was to ensure the joints of the exoskeleton matched the joints of the human. A variety of products have been developed that are able to mimic the activity of the shoulder, elbow and wrist joints, however, it was more difficult to produce an exoskeleton that also stimulates movement of the fingers [77]. An exoskeleton was able to simulate the movement of the shoulder, elbow and wrist joint, as well as allowing the opening and closing of the hand [78]. Other problems that arise from the joints include limited movement of multiple rotary joints [79] and misalignment between the exoskeleton and human limb [77].

The design of an exoskeleton also needs to consider how the user initiates actions performed by the device; this is known as the human-robot interface [77]. The location of the interface should avoid areas sensitive to pressure to ensure that the user is comfortable and safe while using the device. The interface should also be placed in areas without high soft tissue content as this would ensure the attachment is more stable. The control model should replicate the mechanical properties of the soft tissue at the interface to improve the control performance of the device.

A variety of innovations have been developed to provide an interface between the human and the exoskeleton. A device was made which used a vision sensor; this technology used environmental data from sonar sensors and stereo camera to modify the movements of the user [80]. Another product was built that used non-invasive cameras to register the head gesture and mouth expression of the user and convert this information into commands for the machine [81]. One design consisted of a sleeve with embedded optical markers and vibration actuators; this device continually measured the location of the user's arm in the environment, provided visual feedback about the desired and actual arm configurations on a monitor and used intuitive vibrotactile cues to guide the user's arm into the desired position [82]. Another device consisted of clothes with embedded with electroactive polymers that were able to sense straining of the clothes and allowed actuation [83].

A design for an exoskeleton would also need to consider actuation. The majority of exoskeleton technology uses electromagnetic motors to achieve actuation [77]. An alternative is the pneumatic muscle actuators, whereby two pneumatic muscle actuators are used at each joint to create a bidirectional movement. The pneumatic muscle actuators have a high power-

to-weight ratio, compliant, safe, are able to operate in a wide range of environments and allow accurate control of position, motion and force. The pneumatic muscle actuator also presents with problems. The models of force response are very complex and can make it difficult to form accurate designs; also, the device has a low bandwidth, which can limit the ability of the technology to respond to command signals [84].

Other exoskeletons use different methods to achieve actuation. One device used electroactive polymers to actuate the exoskeleton [83]. Another device consisted of a shirt and glove that used conductive elastomer sensors to identify the posture of the user's upper limbs. This technology was being improved by changing to use dielectric elastomer actuators [77]. Alternatively, passive exoskeletons are available which use actuators that are only able to generate resistive force. The passive exoskeletons are lighter and safer than devices that actuate using motors; however, the technology is unable to actively assist movement [85].

An important aspect of exoskeleton function is how the user is able to control the device. Common methods of control are position control and impedance control, with gravity and friction compensation controllers to reduce the effects of gravity and friction on the device [77]. Other devices have used admittance control technology [86].

Other devices have also been developed which used for advanced methods of control. One exoskeleton used a proportional derivative control, if the device was in passive mode, and a neuro-fuzzy based biological controller if the device was in active mode [87]. Another device was able to function using either a nonlinear computer computed torque control [88] or a nonlinear sliding mode control [89] to track the trajectory of passive arm movements.

An innovative addition to exoskeleton technology would be the development of adaptive control strategies. These control strategies can be used to limit the effect of variability between different users and for the patient's individual needs. Examples of variations that can affect the performance of exoskeletons include mechanical properties of the muscles and connective tissues, influence of soft tissue during load transfer at the human-robot interface, and the type and level of weakness of each of the user's muscles. The effect of many of these factors can be prevented by ensuring the human-robot interface is sufficiently connected to the body or by designing algorithms that allow the device to adapt to the body's individual physiology [77].

A device was created that was controlled using EMG that incorporated adaptive control strategy. The device used EMG signals to determine how the user intends to move their arm [90]. An individual's EMG readings may change due to alterations in the placement of electrodes, fatigue, etc. An adaptive control strategy was created which used a combination of multiple fuzzy-neuro controllers and adaptable neural network control. The fuzzy-neuro controllers were activated by the positions of the wrist and forearm. Multiple fuzzy-neuro controllers were used as these would limit the effect of different arm positions on the ability of the device to receive impulses.

Another aspect of the exoskeleton that needs to be considered is the method of powering the device. Current exoskeleton technology uses power supplies with insufficient energy density. Many exoskeletons also rely on using the lower limbs of the device to carry the weight of the actuators and the power supply. The source of power needs to be developed in future exoskeleton designs to ensure that the new devices function at an optimal level [77].

Specific exoskeletons have been designed for use by the lower limbs. Lower limb exoskeletons can be separated into two categories, leg, ankle and foot robots and walking (or gait) robots. The exoskeletons were developed to allow the patient to perform repetitive, resistive and assistive exercises. Many of the exoskeletons consisted of orthoses attached to a bed or couch which allowed the patient to exercise while resting at home or in a hospital environment [91]. One device used mechanical arms, driven by electric motors and controlled using a computer, to copy techniques used by therapists to recover walking motion [92].

Exoskeletons for the lower limbs use either a hybrid control method or impedance control method. Impedance control is defined as a system of control that uses the external forces of the environment to control the position and force of the device. Other control methods have been developed as well. One device used a force-field on the foot, which allowed the exoskeleton to resist or assist the motion of the leg [91]. Another exoskeleton used virtual walls to keep the patients legs moving along a path, which allowed the patient to control the timing of their leg movements [16].

Exoskeletons were very complex and expensive systems. An alternative would be to use a simple device that encourages the user to walk using the user's own movements.

2.2.4 Parallel Bars

Parallel bars are the most basic form of mobility training. The device helps people regain balance, strength, range of motion, independence and recover from injury. The device consists of two bars, parallel to each other, raised to waist level, which the user can hold while performing movements that use more than one joint and muscle. This technology has been proven to be a useful method of rehabilitation. The device requires the involvement of two therapists to move the user's legs; therefore, it cannot be used by the patient independently and also requires commitment and substantial effort on behalf of both the user and therapists [2].

Other technology was available that provided support needed to practice walking, but performed a more active role in determining the precise movements of the user during walking.

2.2.5 Treadmill-training Devices

Treadmill-training devices use a treadmill during mobility training. These devices function by the patient re-learning walking movements through repetition and task-orientated training [2]. This technology allows the patient to concentrate on the lower limb movement, rather than balance, during walking (Fig. 4). Some devices also utilise a partial body-weight support to support the user's body weight and lighten their load during walking.

Fig. 4, an example of a treadmill-training device [17].

The main function of treadmill-training devices was to encourage users to re-learn to walk [51]. Teaching the user to walk can be accomplished using a number of gait training activities (Table 3).

Table 3, a table to display the methods of gait training and how previous devices have performed the activity

Gait Training Activity	Description	Methods of Incorporating Activity into Device
Trajectory tracking	Proportional feedback position controllers and joint angle gait trajectories are used to guide the user's limbs on a fixed trajectories	Teach and replay (trajectory is recorded during manual assistance and repeated during robotic assistance) and adaptive robot (device only provides force if needed)
Impedance control	Position of the device and inner force are used to control force exerted by actuators to move the machine	Triggered assistance (device activates if user is unable to complete movement) and force field control (keeps movement along a virtual path)
Adaptive control	Motion of the device initiated by physical interaction between user and device, allowing the user to control the motion of the machine	Teach and replay (data from manual exercises between user and therapist are used to programme the device) and algorithms

A variety of treadmill-training devices have been developed. One device used a driven gait orthosis that moved the legs of the user in a physiological movement on the treadmill [38]. The orthosis was adjustable, allowing different users to use the same device, and used a position controller to control actuators at the knees and hips. The device was shown to produce physiological gait patterns with patients with various degrees of paresis and spasticity. The device also uses adjustable speed, depending on disability, which allows the patient to move faster. This faster speed has been shown to improve stance duration, stride length and speed of the user. A limitation to this device was that it was difficult to backdrive using the device due to the mechanism of the actuators.

Another treadmill-training device incorporated a leg exoskeleton into the design. The device used a freely translatable and 2D-actuated pelvis segment with a leg exoskeleton with three actuated rotational joints at the hip and knees [93]. The device also had two control systems, one where the exoskeleton is guided by the patient's own movements and one where the exoskeleton controls the movements of the user's legs. It was demonstrated that the movements of the patients using the device mimicked the movements of a person using a

treadmill without an orthosis. This technology did not provide any actuation for the ankle joints, which can impede how the exoskeleton is controlled

A treadmill-training device was developed that used motors at the hip and knee joints. This device based the mechanism to control the speed on the stance ankle. It was demonstrated that this method of speed control reduced the amount of time needed for the user to learn how to use the technology [39].

One device used a gravity balancing orthosis. The gravity balancing orthosis is a device that does not use mechanical actuators, instead a parallelogram mechanism was used to locate the centre of gravity and special springs are used to balance the force of gravity. The orthosis used a force-field controller, made up of position encoders and force sensors, to assist the movement of the patient [94]. The device was lightweight, safe, used less force and the patient produced a normal gait, with an increase in size of stride, larger excursions of the knee and ankle joints and increase in walking speed [95].

Another device was developed that used two moving coil brushless linear servomotors attached to a waist high bar via a V-shaped linkage to move the legs of the user [40]. The position of the moving coils was measured using a linear optical encoder. The advantages of the device was that it was lightweight, accommodates a large step size and produces a large bandwidth (which allows the device to only use a much force as needed to complete the task). A number of safety considerations were also built into the technology. These included safety checks that were able to stop the device if the device became unsafe, such as position-limit checks to ensure the coils are within a safe workspace, velocity checks if the user moves too fast and force limits to prevent the device applying too high a force on the user. The device also has an emergency stop button and a harness, attached to overhead bars, which the user wears to ensure they do not fall. The device was limited because it can only be applied to the ankle and knee joints.

Another treadmill-training device was designed to produce a more natural movement when used. The new design consisted of two devices, one device that fits around the pelvis to assist pelvic motion and a device that is attached to the knees to assist leg swing and prevent knee buckling during walking [96]. The device moved the user's body with pneumatic actuators that were controlled using non-linear force tracking controllers that controlled the flow of gas within the device. A problem associated with this device was that the movement of the legs and the machine became unsynchronised, therefore, an algorithm was introduced which

ensured the legs moved in time with the device. The device also required a long time for to secure the user to the equipment. The machine also required at least some help from a therapist and was unsuitable for independent use.

Another device was developed that used pneumatic muscle actuators. Pneumatic muscle actuators, like skeletal muscles, generate forces during contraction and are light weight and capable of producing large amounts of power with little weight [53]. The actuators were able to provide actuation at the hip and knee joints through double groove aluminium discs. A proportional digital pole placement controller was used to control the device. A number of safety features were also incorporated into the design, such as mechanical stops to prevent the legs being overstretched, an independent safety circuit that powers down the machine if the subject becomes endangered or uncomfortable and emergency stop switches that can deactivate the device. The device was lightweight, simple, easy to wear and did not cause pain or discomfort when used, however, the device will need to develop a function whereby the user can control the assistance provided by the machine.

Another treadmill-training device is called the Lower Body Positive Pressure chamber. This device uses a treadmill encased in a waist-high pressure chamber [17]. The user stands in the chamber and the pressure is increased inside the box until the pressure difference around the user's waist seal produces an upward force that unloads the weight of the user's body. This allows the user to walk along a treadmill without having to carry their weight. Using a Lower Body Positive Pressure chamber was found to lower the user's heart rate, was comfortable and the user was able to run using the device. The Lower Body Positive Pressure was found to change the gait of the user by reducing cadence and shortening stride length.

A number of limitations were identified with treadmill-training devices. The main problem with the design of treadmill-training devices was the location of the actuators. Some devices used an actuation device that was separate from the orthosis, but was linked using cables, rigid linkages and pneumatic or hydraulic systems. These actuators could be larger and more powerful as they would not affect the function of the orthosis, however, the actuators could be affected by inefficient transfer of power, non-durability of cables linked to the actuator and a lack of precise control over the orthosis [47].

The actuator could be directly attached to the orthosis. These actuators achieve an efficient transfer of power and the joints of the orthosis aligns with the joints of the user, however, the weight of the actuator makes the orthosis heavier, which can limit how powerful the actuator

can be and affect the amount of movement that can be applied to the joints. The increased weight of the actuator can be lessened using gravity balancing techniques that lighten the orthosis [47].

A number of treadmill-training devices have been shown to cause effects in a wide range of users. Young children with cerebral palsy were found to learn walking skills quicker and required less support while walking if they used a treadmill-training device twice a day [42]. A cable-driven robotic treadmill-training device was found to improve walking speed and balance of patients with incomplete spinal injury [43]. Another device used a treadmill-training device in front of a television screen to simulate the sensation of the user walking down a street, this machine was found to improve the gait and balance and increase the walking speed of patients following a stroke [44].

Treadmill-training devices were also used to help Down syndrome patients. Children suffering from Down syndrome were found to have poor running speed, balance, strength, visual motor control and overall gross and fine motor control. An important aspect of performing functional skills is balance control as it allows the body to recover from actions that affect balance. The poor balance control exhibited by Down syndrome children may be caused by decreased muscle strength, range of movement, sensory organisation, multisensory integration, cognition, motor coordination and abnormal muscle tone. It was found that using a treadmill-training device improved the balance of Down syndrome patients as it encourages the user to walk so that the lower limbs bear the weight, which allows them to build up strength during walking. Using the treadmill-training device also required the user to walk more with two feet on the ground and this can increase the base of support, which can improve the balance and stability of the user [45].

It was found that the use of treadmill-training devices improved the cardiovascular function of spinal injury patients. A lack of physical exercise has been identified as a major risk factor for cardiovascular disease. The loss of physical function exhibited by spinal injury patients has been shown to limit sufferers performing physical activity. The subjects underwent a six week rehabilitation programme using a device that supported the user's body weight using a harness and controlled the user's leg movements through an exoskeleton. It was found that using the device improved the systolic and diastolic functions of the left ventricle. Coronary flow reserve increased and levels of asymmetric dimethylarginine in the plasma decreased,

which are indicators of improved coronary function. It was also observed that the treatment was more efficient if it took less time to implement it after the injury occurred [46].

Treadmill-training was also found to be a more effective method of treatment than over ground gait training. Two groups of subjects, suffering from spinal injury, were treated for four weeks using either a treadmill-training device or over ground gait training. Both techniques were found to improve the gait performance of the subjects, but the patients treated using treadmill-training equipment was found to show a higher level of improvement [41].

An alternative to the user walking on a treadmill would be to allow the user to walk over ground.

2.2.6 Ambulatory-training Devices

Ambulatory-training devices are similar to treadmill-training devices. Ambulatory-training devices, unlike treadmill-training devices, do not require the use of a treadmill, instead it uses over ground training (Fig. 5). These devices use less equipment than treadmill-training devices. This technology provides dynamic assistance to help the movements of the user and allows the user to walk with the proper upright posture [2].

Fig. 5, an example of an ambulatory-training device [2].

One device consisted of a wheeled frame and harness. The user was able to fit into the harness, which supported the user's body weight, and walk along the ground. The user was also able to hold onto the frame for extra support. This device could also be fitted with a treadmill to allow the user to walk at different speeds. This form of training was found to improve gait and increase heart rate, but the user's found it uncomfortable and it was not recommended for extended training periods [17].

An ambulatory-training device was developed that focussed on the user's trunk. The device used a wheeled tripod frame that used telescopic bars to allow adjustment based on the height of the user [48]. It also used three elastic suspensors to connect between the frame and the lumbar belt, these suspensors allowed free movement of the pelvis. The device also used a lumbar belt to support the user, which could also incorporate a harness if extra support was needed. The device was designed to be used in both clinical and home environments, suggesting that the device was capable of being used independently.

The device that focussed on the user's trunk was tested on the target population. The device was considered safe and the users did not require extra support [48]. The subjects were able to walk using the device and showed improvement in walking speed and stance and swing phases. It was also possible to combine the device with functional electrical stimulation and other orthoses. It was suggested that the device could be improved by adding a harness between the legs to allow the user to rest while using the device.

Another device used a combination of harness and wheeled frame. The harness used in this device could either encircle the waist or support the hips. The frame could either completely surround the user or have an open front and upright sides. A series of cable segments and angle bracket members connected the frame to the harness. The device was also adjustable to fit the height of the user [48].

An ambulatory-training device was developed that moved using a combination of force from the patient and stimulation of the muscles. The device was created using a variety of components. The leg orthosis consisted of a modified shoe, two parallel bars (with rotating ball screw) connected to the thighs and a pair of two stage crank and connecting rod systems to allow movement at the ankle and knee joints. The pelvic orthosis used six actuated axes, each equipped with a motor. Bodyweight support was provided by a harness attached to two motors to control body unloading at both a constant level and during walking. The frame of the device provided deambulation. Force sensors were placed on the leg orthosis, pelvic

orthosis and body weight support to monitor the amount of force exerted on the body and monitor the amount of electrical stimulation applied to the user. The device also used a potentiometer and position sensors [97]. A functional electrical stimulation machine was encased within the leg orthosis and connected to seven pairs of surface electrodes placed on the user's thighs and shanks to move the legs and monitor the force provided by the electrodes [98].

A device was designed to allow the patient to practice challenging movements without exposing the user to risk of falling. The device was specifically designed to help a therapist treat a patient, rather than replacing the therapist. The device was also designed to challenge the user, without the user being at risk of falling. The equipment consisted of two major components: a mobile base system and a brace system. The mobile base system was driven using passive sliders and force sensors located in the pelvic part of the brace, which detected how the user intended to move. The base system was able to move in any direction, could fit through doorways and could be adapted to allow the user to sidestep. The brace system fits around the user's pelvis and torso. The harness around the pelvis controlled the movement of the device, prevented falling and supported the user's weight. The brace around the torso prevented collapse of the trunk. The brace system was also designed to be comfortable, quick to set up and safely challenge the user's balance. The equipment also allowed the therapist to change the machine's control over the user's posture and stability by altering the amount of force and support applied by the device to the user's torso [49].

This device was shown to provide a number of benefits to the user. The device used a special mode that caused the equipment to accelerate from rest to a designated target speed in a small amount of time. This caused the user to walk at a faster speed. The device was also able to detect any drop in the height of the user's pelvis and would catch the user in the harness and stop the user moving forwards, which would prevent the user falling. Using this special mode was shown to increase the walking speed of the user to a faster rate than using over ground training or a treadmill-training device. The device was also shown to increase the step length and cadence of the user. It was suggested that the benefits of using this device were caused by the harness easing the user's fear of falling while using the equipment and the effect of controlling the user's walking speed [50].

An ambulatory-device was created that used a belt, rather than a harness. The device consisted of four components: a mobile base, a system of body weight support, an intention

analysis system and a system that provides safety [99]. The mobile base also used two operational modes, training (this is when the machine generates a set path for the user to walk) and working (this is when the device follows the motions of the user). The height of the mobile base can be adjusted for each user. The body weight of the user was supported using a robotic arm that connected from the mobile base to the user's shoulder. The device was driven using two linear potentiometers within the base to sense the motion of the user and use this data to determine the speed and direction of the device. Four ultrasound range sensors were placed on the equipment to detect nearby obstacles and stop the device to avoid collisions. This device was found to be comfortable and convenient when used.

Another ambulatory-device consisted of a vehicle that fitted round the user. The device was consisted of four aspects: a mobile platform, a pneumatic body weight support mechanism, an intention analysis system and a system that provides safety [99]. The mobile platform was designed to fit around the user's body, with two rotary arms mounted either side of the device that can be adjusted to fit the height of the user. The user's body weight was supported using a harness connected to two pneumatic actuators on either side of the vehicle. The pneumatic actuators were controlled independently to allow the machine to compensate for the alternating movements of the user. The equipment used two accelerators and an electronic compass to measure the linear and angular velocities of the user and moves to reflect the user's intentions. The device was also fitted with four ultrasound range sensors to detect nearby objects and stop the device to prevent collisions. An ultrasound range sensor was also mounted on the front of the device to compensate for measurement errors created by the accelerators and electronic compass. This device was found to be safe and the method of body weight support was found to be effective at maintaining constant force unloading.

A number of benefits were associated with the use of ambulatory-training devices. Gait training using an electromechanical system was shown to improve lower-limb function in a range of users. Users with incomplete spinal injury or had a recent injury (if it was less than six months) were found to show a greater improvement [51]. Ambulatory-training using functional electrical stimulation and over ground training was found to cause a greater improvement in chronic spinal injury patients than using treadmill-based training devices [52].

Other devices did not rely on the user moving over a surface. Instead, a number of devices function by directly moving the feet of the user.

2.2.7 Feet-Manipulator Training Devices

Feet-manipulator training devices help train the user's mobility by focussing on the feet. The user's feet are attached to robotic manipulators that support and gently simulate walking. The user wears a harness attached to a steel frame and rests their feet on plates. The plates can be programmed to imitate walking situations, such as walking on level ground, tripping, slipping or using stairs (Fig. 6). Practice of walking movements exercises the slack muscles between the hips and toes [2].

Fig. 6, An example of a feet-manipulator training device [2]

One device used a planetary gear system to control the movements of separate footplates. Manipulating the feet separately allowed the machine to simulate foot motion during walking [100]. Each footplate was positioned onto a bar and connected to a rocker and a crank that provided the propulsion. A planetary gear system (which consisted of a sun and planet gears) was connected to the footplates to ensure that the user walks at a faster pace. A control unit was also built into the device to detect the velocity of the machine and a motor was able to provide assistance if the user was not moving at the required velocity. The torque generated

by the device was sensed and displayed by the equipment to provide a biofeedback signal for the user and therapist.

Cadence and length of stride could be changed depending on the user and the centre of mass can be changed using ropes attached to the harness [56]. The device allows the therapist to maintain physical contact with the user and perform minor corrections to the knees. The device can also use a programmable eight-channel functional electrical stimulation system to control the knee or assist push-off while walking. The device also allows more movement of the legs by using less constraining leg attachments.

Another feet-manipulator training device used freely programmable footplates. The footplates were moved using two robot modules and a linear direct drive motor positioned on a rail connected to both footplates through a slider-crank system [57]. A robot arm (containing a rotary motor) was used to turn the footplates. A trunk suspension module was also added to the machine to suspend the user's trunk, prevent falls and move the centre of mass to enable walking. The device was able to be programmed so that the stride length, step height and cadence can be changed for each user. The machine was able to provide feedback on the position, force, torque, motor current and digital I/O of the user and device. The device was also able to provide a 3-dimensional visualisation of the foot position and contact force of the user. The equipment also incorporated a number of safety measures, such as a manual emergency switch and automatic emergency switches that would be able to stop the device.

A feet-manipulator training device was developed that used two motion platforms instead of footplates. Each motion platform had a footpad on the top that user stood on while using the device [58]. Position sensors measured the position of the user's feet and AC servomotors used optical rotary encoders to measure the position of the footpads. The device was controlled using a computer. The machine was designed so that the footpad follows the user's foot while moving and the other foot would be moved backwards the same distance as the other foot would walk forwards. The device was also able to move the feet to follow a normal walking motion without any effort from the user and the trajectory, stride length, step height and walking cycle enforced by the equipment can be changed. The machine was surrounded by a safety frame and a safety belt was attached to allow the user to use the device without endangering themselves. The safety frame was also designed to allow the user to pull themselves up a small number of wide steps to access the equipment. The device was shown to encourage users to walk independently and it allowed the therapist to concentrate more on

teaching walking motions, rather than physically moving the user's legs themselves. The machine was also able to produce quantitative data on the progress of the user and it can also be used remotely.

Another feet-manipulator training device considered simulating walking over different terrain. The foot plates contained force sensors that were able to ensure the user was in contact with the foot plates at all times [54]. The foot plates were able to simulate walking over different terrains by permitting high bandwidth responses, being coupled to the user's feet and using an advanced control system. The device was able to support high bandwidth responses so that it was able to respond to the large movements and fast speeds of human motion. Different terrains were simulated by changing the forces applied upwards on the user's feet to reflect the experience of walking over these surfaces underfoot. Coupling of the feet to the foot plates was used to simulate terrains where a downward force was applied to the feet. The attachment of the feet to the foot plates can be accomplished using either a non-controllable method (this is when a technician is needed to attach the feet to the foot plates) or a controllable method (this is when the attachment couples the feet to the foot plates automatically). A non-controllable method of attachment would a strap to tie the user's feet to the foot plates. A controllable method would use computer controlled pneumatic suction cups to control the amount of suction needed to stick the user to the device. An alternative controllable method would be the use of electromagnets and special boots (embedded with soft iron plates) to couple the user to the device. The device also incorporated a number of safety features. Force sensors within the foot plates were also capable of shutting down the machine if contact was lost with the user.

A number of difficulties were associated with the device. The human vestibular system (organs responsible for balance) is very sensitive to changes in the environment and can be affected using the equipment. A second problem is that the user's momentum while walking can be hindered by walking in place. Both of these problems can be overcome by performing a number of training exercises before using the device. The device was originally designed for training in a virtual reality environment; however, it was thought that the device could be easily adapted for use as a rehabilitation tool [54].

A feet-manipulator training device was created to allow walking on different simulated surfaces. The device used two plates, a large one bolted to the floor and a smaller, mobile one attached to the user's foot [55]. Six double-acting pneumatic actuators were connected to

both bases using spherical joints. The machine simulated walking by the platforms following the stepping foot forwards and sliding the passive foot backwards. This was accomplished by switching the control mode between position and force control depending on the movement. A servo control interface was used to change the control mode, slide the foot backwards and coordinating the motion of the platforms. A computer was used to detect collisions and activate the servo control interface when the foot touches the ground. The range of motion of the joints was limited to prevent damage to the actuators and allowing them to maintain a continuous motion.

Not all devices were complex machines which encased the user. Some devices were much smaller and only affected the part of the body unable to move properly.

2.2.8 Orthoses

Orthoses are devices carried by the user to improve the function of movable body parts. Orthoses are designed to offset hindrance to mobility and help the movements of the user. The devices improve the functionality of the affected limbs and allow the user to perform a wide variety of movements (Fig. 7). These devices can either be active (the equipment provides the energy needed to perform movements) or passive (the user moves the limb along with the orthosis) [2].

Fig. 7, An example of an orthosis [2]

A passive orthosis was built that used gravity balancing technology and used the trunk to move the leg. The device was made of aluminium and was attached to the user's thigh and shank using straps [39]. Ball bearings were used at the knee, hip and mechanical joints to reduce friction. The device incorporated a parallelogram-shaped structure into the design to locate the centre of mass and a system of springs and pulleys to balance the effect of gravity over the range of motion. The aluminium limbs were telescopic to allow the machine to accommodate different sized users and the location of the springs was adjustable to change the level of gravity during motion. The orthosis also allowed the trunk to rotate. The thigh segment was positioned inwards at the bottom to prevent the lower end of the device detaching from the body. The hip joint of the device was also made more flexible to allow hip and pelvic movements. The device could be attached to either a backpack or a walking frame.

Simpler devices were available that used less mechanical components and provided support, instead of movement.

2.2.9 Canes

Canes are external devices used to help the user's balance. The canes provide an increase in gait stability and have been shown to prevent falls [2].

Standard canes were produced in two varieties. A single point standard cane used a single point of contact between the cane and the ground. A multi-feet standard cane consisted of a supporting tube attached to a small number of feet that connect to the ground. The multi-feet cane provides a greater amount of stability than the single point cane. A number of limitations have been identified with both canes [2]. The single point cane did not provide retropulsion, which can cause users to fall backwards, and the multi-feet cane can cause some users to trip and fall [18].

A cane was developed that was capable of sensing and avoiding obstacles. The cane used a six-axis force/torque sensor to measure the amount of force and torque applied to the handle by the user [59]. The data was used to determine the velocity and direction the user intended to move, which allowed the cane to move without much effort from the user. The cane rotated by twisting the handle. The control system can also be programmed to provide a different sensitivity for each user depending on need. The device used a camera to determine the location of the cane. The camera registered passive signposts placed within the ceiling. The signposts consisted of an orientation marker, centrepiece marker and identification marker. The cane also used a sonar array to detect any unforeseen obstacles. The cane also incorporated a shared adaptive control mechanism which allowed the cane to guide the user to certain location if the user becomes lost.

A cane was also developed that was able to sense nearby obstructions. The cane used ultrasound to detect nearby objects and the device changed direction to avoid the object. The cane led the user back to the original path after passing the obstacle. The device was controlled using a joystick. The device was also able to detect stairs. The cane also used potentiometers and encoders as sensors. The main servo and brakes were used for actuation [60].

Similar devices were available that provided more support.

2.2.10 Crutches

Crutches are external devices that directly support the body. The crutches provide greater stability and balance during walking. The crutches also provide greater weight support than canes. A number of problems have been identified with using crutches. These problems include the crutches being cumbersome and providing an unnatural gait [2].

Other devices were developed that provided support. These devices were more complex and more mechanical, but required less effort by the user and were smoother.

2.2.11 Walkers

Walkers are external devices that support the user during walking and move using the user's locomotion. The use of the walker increases the user's base of support, which allows the user to maintain a higher level of balance and can change their position more freely. The walkers can also incorporate stabilising reaction forces to improve the stability of the user. Walkers are classified as either conventional (are simply pushed along the ground) or smart (include robotic and electronic components that improve navigation, gait monitoring and weight support) [2].

The standard walker consisted of a metal four-legged frame with rubber tips. The frame must be lifted and placed forwards during walking. This device provides sufficient balance, is easy to use and can bear large weights. This walker does require a certain amount of upper body strength and cognitive ability to use properly and results in an abnormal gait [2]. The device also provides little retropulsion or propulsion, leaving many users falling backwards or unable to move forwards. The walker can also encourage the user to fall forwards while walking [18].

Another walker has wheels attached to the front of the frame. The wheels reduce the amount of strength required to move the device and remove the need to lift the walker. The device also resulted in a more natural gait [2]. This device can be improved if the wheels retract and the legs make firm contact with the ground when the user leans forward [18].

Another type of walker is called the rollator. Rollators consist of a frame attached to a set of wheels that roll along the ground and functions by being pushed [18]. The rollators were made of lightweight and strong materials with wheels that could roll and pivot smoothly, without requiring a large amount of effort. The rollators can use three wheels, four wheels or a U-shaped bar attached to five wheels. Braking can be provided by either hand brakes, that are squeezed, or a padded bar, that is pushed. The rollators can also have additions, such as a seat, a backrest or a basket.

A walker was designed to be able to move up and down stairs. The four-wheeled device had a switch that loosened the device and allowed the user to move the front wheels so they were close to the back wheels. The device became a cane-like structure and could be moved up and down stairs. The wheels became locked to support the user's weight and produced a linear motion [2].

Another device could become compacted. This device used a crank to adjust the velocity of the walker. The height of the walker was also adjustable through a crank mechanism [2].

Standard walkers were mechanical and required the movements of the user to achieve locomotion. Other walkers were developed that used extra robotic and electronic components to improve the user's gait. The electronic parts of these devices were specifically designed to improve the walker's navigation, ability to monitor the user's gait and support the user's body weight [2].

A walker was developed that sensed obstacles. The walker used a six-axis force/torque sensor to measure the forces and torque applied to the device, which was used to move the walker in the correct direction at the appropriate speed [59]. The device used a camera to determine the position of the device by registering passive signposts placed within the ceiling. The signposts consisted of an orientation marker to provide a general location, a centrepiece marker to determine a more specific location and identification marker to provide a highly specific location. The device also used a sonar array to detect any unforeseen obstacles. The device moved using a pair of active spilt offset castors that were attached to the walker's mobility platform, along with a pair of passive wheels for stabilisation. This method of movement allowed the device to function on rough and dirty floors.

A number of additions were built into the walker. The walker used an electrocardiogram-based monitor to check the health of the user. The force/torque applied by the user was used with odometry data to determine the user's gait and predict falls. The user's stride length and frequency was determined using the velocity of the device and to detect if the user becomes injured. The walker also used an adaptive control mechanism, which allowed the walker to guide the user to certain locations [59].

A walker was developed that functioned by detecting sensors within the ground. The device used an encoder, a digital compass, two radiofrequency readers and two radiofrequency antennas [61]. Radiofrequency tags can be hidden under carpets that can be detected by the

antenna of the walker. The walker can interpret data from the tags to produce information on the device's location. The radiofrequency tags can also provide information to programme the digital compass so that the walker can only move down clear pathways and cannot roll into solid obstructions. A user interface was also incorporated into the structure of the device, which consisted of a laptop or small computational unit. The interface provided an audio cue to direct the user. The interface either provided a text cue and large green arrow or a map of the surroundings and a small green arrow to provide direction. The cues were based on information provided by the detection of radiofrequency tags. The walker was also able to provide an alternative route if the user moved in an incorrect direction.

A walker was developed that was designed to enhance the user's ability and not replace them. A motor was attached to the front wheel to steer the walker if the device approached an obstruction. The user controls the speed of the device. The device used sonar and infra-red sensors to detect obstacles and map the surrounding area. This data (along with the orientation of the walker, length of a path and previous walking history) determine the direction the walker moves. Sensors in the handles detect the amount of force applied to each handle and determine if the user intends to change direction. The device also used an automatic braking system to prevent the user colliding with obstacles [62].

A walker was developed that was designed to provide navigation, along with support and stability. The device used two circular arrays of ultrasound transducers, two circular arrays of infra-red near-range sensors and three large touch-sensitive doors to sense obstacles at various heights [63]. The walker was also able to map an environment after it was driven manually with a joystick interface and using a laser range finder. A pair of force sensors was embedded into the handlebars to allow the device to sense the user's intended direction by the amount of force the user transfers to the handlebars, which also provided support and stability. The device also used a number of settings to allow it to adjust for different users: passive mode (user completely controls the walker's direction), active mode (user controls the device, but it also slow down and halts if it goes in the wrong direction) and forced mode (the device controls the direction of travel). The walker also provides help to the user in the less active modes, such as preventing collisions with obstructions, monitoring the user's position and providing a graphical representation of the correct path for the user to follow.

A device was developed that used a new method of guidance control. The walker moved using omni-directional wheels arranged in a specific pattern on the base of the platform to

allow the device to travel in a wide range of directions [64]. A handrail provided support to the user. Sensors on the device measured the amount of force applied to the device and altered the amount of power from the motors. An odometer was used to estimate the location of the device. A laser scanner was used to detect any nearby obstacles and allowed the machine to perform a number of autonomous functions. The methods of autonomous navigation included obstacle avoidance (device avoids obstacles), wall following (walker moves in the same direction as a nearby wall) or goal seeking (machine follows a pre-set path to reach a specific location). An inclinometer was also built into the device.

Devices were also developed that dictated how the user stood, instead of providing support during walking.

2.2.12 Standing Frames

Standing frames are external devices that allow the user to stand. The standing frame provided external support and secured the knees and hips to allow the user to remain in a passive standing position [18]. Standing frames can be stationary or wheeled. Wheeled standing frames have been shown to improve independent mobility and strengthening by allowing the user to propel themselves along level surfaces [14].

A standing frame was developed that functioned as an extension of the user's wheelchair. The arm rests of the wheelchair contain tubes that can be extended forwards and locked into position [101]. The support resembles a walking stick and is located within the tube. The support then unfolds and slides down the front tube to securely support the hinge (which is located within the tube). The device also has a clamp to attach the arm rest to the back of the wheelchair. A spigot was placed on the arm rests using a lock nut. The clamp and spigot allowed the user to adjust the height of the standing frame. The spigots were situated at the same angle as the user's arm to increase the user's base area and reduce the effect of lateral forces. The frame was designed to be light, be able to fold safely and easily and be able to lock position after folding.

Appendix D – Scope of Technology to Help Spinal injury Sufferers

Body	Technology	Picture	Type	Description	Origin (who?/where?)	Reference	Benefits	Limitations	Examples of Devices
Muscle	Functional Electrical Stimulation		Shallow	Electrodes are placed on leg muscles and cause electrical stimulation. This activates the muscles and allows walking.	Cleveland FES Center	BrainandSpinalCord.org	Improves hip extension, foot swing and foot clearance. Walking velocity incereses due to stride lengthing and using more steps.	Needs to be implanted for permanent use	FES cycling machine, FES rowing machine, Hybrid FES rowing, Tricycle, BION
			Deep				Improves hip extension, foot swing and foot clearance. Walking velocity incereses due to stride lengthing and using more steps.	Needs to be implanted for permanent use	
	Locomotor Training		N/A	Re-teaches walking using body weight support and a treadmill system along with manual assistance by specially-trained physiotherapists.	NeuroRecovery Network (across USA)	Kessler Institute for Rehabilitation	Improves walking speed and distance	Difficult to standardise walking measurements. May be dependent on walking devices.	
Mobility assistive	Wheelchairs		Manual	A vehicle that is used to help the user travel using either a manual process or an autonomous system	Drive Medical Limited (UK) and Karma Mobility (UK)	Martins, M. M.; Santos, C. P.; Frizera-Neto, A.; & Ceres, R. (2012). Assistive Mobility Devices Focusing on Smart Walkers: Classification and Review. *Robotics and Autonomous Systems*, 60, (4), 548-562.	Optimal solution for people suffering from total incapacity of mobility	Can cause physiological problems by user constantly being in a sitting position	Manual wheelchair
			Autonomous		University of Porto (Portugal)	Reis, L.; Braga, R.; Sousa, M.; & Moreira, A. (2010). IntelWheels MMI: a Flexible Interface for an Intelligent Wheelchair. *Lecture Notes in Computer Science*, 5949, 296-307.			Robotic wheelchair
	Parapodium		N/A	A prefabricated standing frame worn over the clothes that consists of a spring-loaded shoe clamp, aluminium upright, a foam knee block and chest panels	Orthos International B. V. (Holland)	www.physability-uk.com	Decreases the load on the activated leg and enables movement without friction between the foot and the floor. Allows the user to feel safe and secure. It has also been shown to: reduce muscle spasms, improve the respiratory system, improve cardiovascular function and thermoreoulation, improve organ function.	Hands are only free when standing still, therefore, the user cannot walk while holding anything. User needs lessons to learn how to use device. The device forces the users legs to swing with each step.	Parapodium
	Exoskeleton		N/A	User is encased in a robotic skeleton that allows the human to control movement, but aided by robotic muscles	Raytheon (USA) and Lockheed Martin (USA)	Hanlon, M. (2010). Raytheon XOS 2: second generation exoskeleton. *Gizmag*.	Can improve the muscle power of user, even those with limited muscular capability. Does not require special training to use as it is controlled by the user's movements. The legs can be removed so, if fuel runs out, the device just becomes a backpack and can be moved. Can have additional equipment added to allow vertical takeoff and landing	Cannot perform complex movements, such as running and jumping. Is either powered by a potentially dangerous fuel source that doesn't provide enough energy for extended use or by a tethered power source that limits how much distance the user can cover.	ARMin, TEM, Path Control, MIT-MANUS, MIME, GENTLE/s, IntelliArm, CADEN-7, WREX, ExoRob, W-EXOS, Physiotherabot, HAL, Mechanized Gait Trainer,
Mobility Training Devices	Parrallel Bars		N/A	Users hold to a pair of parrallel bars and repeat concise movements that exercise more than one joint and muscle	Clinton Industries (USA) and Hausmann Industries (USA)	QuickMedical	Has proven to be successful in rehabilitating patients suffering from disability	Requires involvement of one or more physiotherapist. Does not provide realistic walking conditions. Patients may rely on it if used for too long.	Parallel Bars
	Robotic mobility-training devices		Treadmill-training Devices	Uses a treadmill to encourage users to re-learn walking through repetition and task-orientated training	The Lokohelp Group (Germany) and Hocoma (Switzerland)	Martins, M. M.; Santos, C. P.; Frizera-Neto, A.; & Ceres, R. (2012). Assistive Mobility Devices Focusing on Smart Walkers: Classification and Review. *Robotics and Autonomous Systems*, 60, (4), 548-562.	User does not have to concentrate on balance and can focus on lower limb movement.	User has to be intensively engaged in procedure, easy to lose interest. Harness used to support body weight can cause discomfort. Requires great physical effort on behalf of therapists.	LOPES, ALEX, Lokomat, Lokohelp, LiteGait, Spring Flamingo, M2, ARTHuR, Pelvic Assist Manipulator, Pneumatically Operated Gait Orthosis, AutoAmbulator,
			Ambulatory-training Devices	Uses over ground training to encourage users to re-learn walking through repetition and task-orientated training	Mobility Research (USA) and Kinea Design (USA)	Martins, M. M.; Santos, C. P.; Frizera-Neto, A.; & Ceres, R. (2012). Assistive Mobility Devices Focusing on Smart Walkers: Classification and Review. *Robotics and Autonomous Systems*, 60, (4), 548-562.	Uses less equipment than training-assisted devices. User learns to walk with proper upright posture	User has to be intensively engaged in procedure, easy to lose interest. Harness used to support body weight can cause discomfort	Walkaround, WalkTrainer, KineAssist, LiteGait, Where-I, Where-II, Standimovi, AID-1, REHABOT,
			Feet-manipulator Training Devices	A robotic manipulator supports and gently leads the users feet in a continuous practice of walking situations	Rifton (USA), Fraunhofer Institue (Germany) and Sant'Anna School of Advanced Studies (Italy)	Martins, M. M.; Santos, C. P.; Frizera-Neto, A.; & Ceres, R. (2012). Assistive Mobility Devices Focusing on Smart Walkers: Classification and Review. *Robotics and Autonomous Systems*, 60, (4), 548-562.	Can be used with a wheelchair and stimulates different situations. Forces muscles into action.	User has to be intensively engaged in procedure, easy to lose interest. Harness used to support body weight can cause discomfort	HapticWalker, GaitTrainer
Self-ported Devices	Orthoses		N/A	A device carried to improve the function of a moveable part of the body by either mechanically compensationg or enhancing the functionality of the damaged limb. They can be active or passive. Active orthoses function by using motors to produce the energy needed to enable movement. Passive orthoses function by the user producing enough energy to move the device.	Argo, Medical Technologies, Ltd. (China), Yobotics (USA), Massachusetts Institute of Technology (USA), Technical University of Madrid (Spain)	Martins, M. M.; Santos, C. P.; Frizera-Neto, A.; & Ceres, R. (2012). Assistive Mobility Devices Focusing on Smart Walkers: Classification and Review. *Robotics and Autonomous Systems*, 60, (4), 548-562.	Present an intensive physical and cognitive interaction with the user to ease the loss of mechanical function of a limb.The device allows the user to perform a large number of functions, such as standing, walking and climbing stairs. The device improves the dignity, inclusion, health and self-esteem of the user.	Can be uncomfortable for the user and may be difficult to use. Can also affect the aesthetics of the user.	RoboKnee, MIT active ankle-foot orthosis,
External Devices	Canes		N/A	Used to help users with balance problems and provides a weight-support.	Massachusetts Institute of Technology (USA) and University of Michigan (USA)	Hoo, F. W.; Demonbreun, D.; & Weiss, B. D. (2003). Ambulatory Devices for Chronic Gait Disorders in the Elderly. *American Family Physician*, 67, (8), 1717-1724.	Can be available as robotic devices that sense the desired pace and direction of the user's walk. They can also detect obstacles in the path of the user.	Provides little support, so that the user is likely to fall over using the device.	Standard Cane, Multi-feet cane, Smart cane, Guide cane
	Crutches		N/A	Used to help users with balance problems and provides a weight-support.	SmartCRUTCH (UK)	Hoo, F. W.; Demonbreun, D.; & Weiss, B. D. (2003). Ambulatory Devices for Chronic Gait Disorders in the Elderly. *American Family Physician*, 67, (8), 1717-1724.	Provides stability and balance while walking. The device also provides an improved weight support compared to canes.	Are very cumbersome and are being used less because they provide an unnatural gait.	Standard Crutch
	Walkers		Conventional Walkers	Has four rubber tips that are lifted and then placed on the ground for the user to walk. Can also be available with four wheels instead of tips that the user pushes along to walk with.	MobilitySmart (UK) and In-Step Mobility Products, Inc. (USA)	Constantinescu, R.; Leonard, C.; Deeley, C.; & Kurian, R. (2007). Assistive Devices for Gait in Parkinson's Disease. *Parkinsonism and Related Disorders*, 13, 133-138.	Easy to use and can come with extras that helps the user cary out other functions. Depending on the walker chosen, gait patterns and walking speed can also improve. Some walkers can also be used to help the user go upstairs.	Some walkers require a high upper body strength and cognitive ability to operate safely. They can also produce an unatural gait and can increase the risk of falling, either due to the user falling backwards or the walker being the direct cause. A large percentage of users abandon the device shortly after recieving it. They also require more space and can be difficult when travelling with obstacles or on certain surfaces. They also cause a slower gait and require more energy and greater fitness to operate.	Standard walker, Front-wheeled walker, Rollator, Boomer,
			Smart Walkers	Has four wheels and is pushed along by the user. It also has additional electronic components that can provide extra assistance to the user based on either physical support, sensorial assistance, cognitive assistance, health monitoring or advanced human-machine interface.	Bioengineering Group of CSIC (Spain), Trinity College (Ireland), University of Virginia (USA), Technical University of Catalonia (Spain), Massachusetts Institute of Technology (USA),	Martins, M. M.; Santos, C. P.; Frizera-Neto, A.; & Ceres, R. (2012). Assistive Mobility Devices Focusing on Smart Walkers: Classification and Review. *Robotics and Autonomous Systems*, 60, (4), 548-562.	Provides a greater support to gait. Certain devices can provide a greater gait stability to the user by having a heavier base, which also makes it easier to push. Devices are also available that sense obstacles around the device, making the user safer. Other devices can guide users back to their homes, helping the user return if they suffer from cognitive difficulties. Some Devices can also monitor the health of the user, allowing them to become more independent. The devices can also interact more with the user, allowing them to control the device more and allows them to perform other functions with the device.	The user needs to have good strength and coordination to use the device and the braking systems on some the devices are difficult to use and need the user to be suitably quick, strong and alert. Some of the devices alert the user to obstacles, but not stairs, which can be dangerous, and are also unable to detect hazards that are underneath the device. Some of the devices can be very complicated to use and are not suitable with users who have cognitive difficulties. Some of the devices are very expensive and do not provide the correct gait.	U-Step, Mobil walker, ASAS, SIMBIOSIS, Personal Adaptive Mobility AID, iWalker, MARC Smart Walker, Nomad XR4000, ASBGo walker, PAMM smart walker, Guido, Walkmate, UTS, ZJU walker, Sprint, JAIST active robotic walker, Walbot,
	Standing Frames		N/A	A device a user sits on which can then change shape so that so that the position of the user changes from a sitting position to a standing position. The technology keeps the user standing at a comfortable stance until they decide to change.	Altimate Medical, Inc. (USA)	Garvey, K. (2001). Standing Aids: Opportunites and Options. *PN*.	The promotion of standing has a variety of benefits, such as: preventing leg muscle atrophy, improved range of movement, enhancements to circulation, reduced muscle spasms and contractions, maintenance of bone integrity, reduction of lower extremity swelling, increases of endurance and improvement of the circulatory system, prevention of pressure sores, assistance with kidney and bladder function (reducing infection) and improvement in bowel regularity and function. Less need to modify home and work area to accomodate sitting devices and aid to social interaction by interacting at eye level.	Some devices need a carer to help the user into the device.	Stationary standing frame, wheeled standing frame